

# **John Wagner**

## **Supplemental General Reliance List *in Addition to Materials Referenced in Report***

### **MDL Wave 4**

## Medical Literature

Abbott S, et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: multicenter study. <i>AJOG</i> 2014; 210: 163.e1-8.
Abdel-fattah M. Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study. <i>BJOG</i> 2010;117:870-878.
Abdel-Fattah, M, et al., Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications. <i>Eur Urol</i> 2011;60:468-480.
Abdelmonem, A. Vaginal length and incidence of dyspareunia after total abdominal versus vaginal hysterectomy. <i>Eur J Obstet Gynecol Reprod Biol</i> 2010; 151: 190-192
Abdelwahab, O. Tension-free vaginal tape versus Secure Tension-free Vaginal Tape in Treatment of Female Stress Urinary Incontinence. <i>Curr Urol</i> 2010; 4: 93-98
Abduljabbar, H. Comparison of the classic TVT and TVT Secur. <i>Prime Journals</i> 2012; 2(9): 344-347
Afonso. Mechanical Properties of Polypropylene Mesh Used in Pelvic Floor Repair. <i>Int Urogynecol J</i> (2008) 19:375-380
Agarwala. A randomized comparison of two synthetic mid-urethral tension-free slings. <i>Urotoday International Journal Vol 1 Iss 4 October 2008</i>
Agostini A, et al. [Pop 12,280] Immediate complications of tension-free vaginal tape (TVT): results of a French survey. <i>Eur J Obstet Gynecol.</i> 2006; 124:237-239.
Ahn, C. Analysis of voiding dysfunction after transobturator tape procedure for stress urinary incontinence. <i>Korean J Urol</i> 2015; 56: 823-830
Aiguellier T, et al. [10 yr fu] Ten-year follow-up after the tension-free vaginal tape procedure. <i>Am J Obstet Gynecol.</i> 2011; 205:496.e1-5.
Ala-Nissila. [Pop 130, mean 8 yr fu] TVT - a suitable procedure for patients with recurrent SUI; <i>Acta Obstetrica et Gynecologica.</i> 2010; 89:210-216
Albo M, Richter, Zimmern, Moalli, Sirs. - NEJM - SISTER study - Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. <i>N Engl J Med</i> 2007;356:2143-55.
Albo, Zyczynski, Lemack. Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months. <i>J Urol</i> (2012) 188(8): 2281-2287
Albrich. TVT-Secur: A novel approach for the treatment of female genuine stress urinary incontinence <i>Int Urogynecol J</i> (2007) 18 (Suppl 1):S25-S105
Alcalay, M. Burch colposuspension: a 10-20 year follow up. <i>British Journal of Obstetrics &amp; Gynaecology.</i> 1995; 102: 740-745
Almassi, N. Intraoperative Ultrasound-Guided Removal of Retained Mini Sling Anchor Causing Vaginal Pain: A Case Report. <i>Female Pelvic Med Reconstr Surg</i> 2015; 1-3
Alvarez, J. Complications in pelvic floor surgery. <i>Minerva Ginecol</i> 2013; 65: 53-67
Amid PK. Biomaterials for abdominal wall hernia surgery and principles of their applications. <i>Langenbecks Arch Chir</i> (1994) 379:168-171
Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. <i>Hernia</i> :1997:1:15-21.
Amorim-Costa. Laparoscopic-Assisted Retropubic Midurethral Sling Placement: A Technique to Avoid major Complications. <i>The Journal of Minimally Invasive Gynecology</i> (2016), doi:10.1016/j.jmig.2016.03.011
Anger, J. Trends in the Surgical Management of Stress Urinary Incontinence among Female Medicare Beneficiaries. <i>Urology</i> 2009; 74(2): 283-287

## Medical Literature

Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo MA. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. <i>Eur Urol</i> 2010;58:671-677.
Aniulienė. TVT-Exact and midurethral sling (SLING-IUFT) operative procedures: a randomized study; <i>Open Med</i> . 2015; 10:311-317
Appelbaum, P. Assessment of Patients' Competence to Consent to Treatment. <i>N Engl J Med</i> 2007; 357: 1834-40
Appell, Dmochowski. Guideline for the Surgical Management of Female Stress Urinary Incontinence: Update, 2009
Arts-de Jong. [Pop 55, 1 yr fu] Improvement of sexual function after transobturator tape procedure in women with stress urinary incontinence. <i>Gynecol Surg</i> (2011) 8:315-319
Aslan, E. Female sexual dysfunction. <i>Int Urogynecol J</i> 2008; 19: 293-305
Athanasίου S. Grigoriadis T, Zacharakis D, Skampardonis N, Lourantou D, Antsaklis A. [Pop 124, 7 yr fu] Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? <i>Int Urogynecol J</i> (2014) 25:219-225
Atis, G. Tissue Reaction of the Rat Urinary Bladder to Synthetic Mesh Materials. <i>The Scientific World Journal</i> 2009; 9: 1046-1051
Aydin, A, et al. Recurrent urinary tract infections in women. <i>Int Urogynecol J</i> (2015) 26:795-804.
Bang, S. Autologous pubovaginal slings: back to the future or a lost art? <i>Research and Reports in Urology</i> 2016; 8: 11-20
Barber, M. Single-Incision Mini-Sling Compared with tension-free vaginal tape for the treatment of stress urinary incontinence. <i>Obstet Gynecol</i> 2012; 119(2)(1): 328-337
Bazi, T. Polypropylene Midurethral Tapes do not have similar biologic and biomechanical performance in the Rat. <i>Eur Urol</i> 2007; 51: 1364-1375
Beckmann, C. Table 47.1 Categories of Sexual Dysfunction in Obstetrics and Gynecology Sixth Edition Chapter 47 - Human Sexuality; 419
Behara. Laparoscopic Findings, Histopathologic Evaluation, and Clinical Outcomes in Women With Chronic Pelvic Pain After Hysterectomy and Bilateral Salpingo-Oophorectomy. <i>J Minim Invasive Gynecol</i> 13 (5), 431-435. Sep-Oct 2006
Bendavid, Iakovlev. Mesh-related SIN syndrome. A surreptitious irreversible neuralgia and its morphologic background in the Etiology of Post-Herniorrhaphy Pain. <i>International Journal of Clinical Medicine</i> , 2014, 5, 799-810.
Bent, A. Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study. <i>Am J Obstet Gynecol</i> 1993; 169: 1198-204
Berger AA, et al. [Pop 227 2 mo fu] The Role of Obesity in Success and Complications in Patients Undergoing Retropubic Tension-Free Vaginal Tape Surgery. <i>Female Pelvic Med Reconstr Surg</i> 2016; 22:161-165
Berger, A. The Role of Obesity in Success and Complication in Patients Undergoing Retropubic Tension-free Vaginal Tape Surgery. <i>Female Pelvic Medicine &amp; Reconstructive Surgery</i> ; 2015
Bernasconi, F. TVT SECUR™ System: Final Results of a prospective, observational, multicentric study. <i>Int Urogynecol J</i> 2012; 23: 93-98
Bezerra. [Full version Cochrane Review] Suburethral sling operations for urinary incontinence in women (review); <i>The Cochrane Library</i> 2001, Issue 3
Bezhenar, V. [ICS ABS 768] 7-Year Old Clinical Experience of Treating Women's Urinary Incontinence Using Suburethral Slings. 2013
Bianchi-Ferraro AM, et al., Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial. <i>Int Urogynecol J</i> 2013 Sep;24(9):1459-65.

## Medical Literature

Bianchi-Ferraro, A. Randomized controlled trial comparing TVT-O and TVT-S for the treatment of stress urinary incontinence: 2-year results. <i>Int Urogynecol J</i> 2014; 25: 1343-1348, doi: 10.1007/s00192-014-2352-7.
Bianchi-Ferraro, A. Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial. <i>Int Urogynecol J</i> 2012; Epub Ahead of Print
Bing MH, et al. Clinical risk factors and urodynamic predictors prior to surgical treatment for stress urinary incontinence: a narrative review. <i>Int Urogynecol J</i> 2014; Epub Ahead of Print
Binnebosel. Biocompatibility of prosthetic meshes in abdominal surgery. <i>Semin Immunopathol</i> (2011) 33:235-543
Birolini C, et al. [case report] Mesh cancer: long-term mesh infection leading to squamous-cell carcinoma of the abdominal wall. <i>Hernia</i> (2013).
Black, N. The effectiveness of surgery for stress incontinence in women: a systematic review. <i>British Journal of Urology</i> 1996; 78: 497-510
Blaivas, Iakovlev. (corrected in color) Safety considerations for synthetic sling surgery. <i>Nat. Rev. Urol.</i> 12, 481-509 (2015)
Blaivas, J. Ch. 17 Pubovaginal Sling. <i>Female Urology</i> , edited by Elroy D. Kursh and Edward McGuire. J.B. Lippincott, Philadelphia, 1994; ISBN 0-397-51154-X
Blaivas. Pubovaginal Fascial Sling for the Treatment of all Types of SUI: Surgical Technique and Long-term Outcome. <i>Urol Clin N Am</i> 38 (2011) 7-15
Blaivas. Pubovaginal fascial sling for the treatment of complicated SUI. <i>J Urol</i> , 145, 1214-1218, June 1991
Blaivas. Salvage surgery after failed treatment of synthetic mesh sling complications. <i>J Urol</i> Vol. 190, 1281-1286, October 2013
Blandon Article, Complications from vaginally placed mesh in pelvic reconstructive surgery. <i>Int Urogynecol J</i> (2009) 20:523-531.
Blitstein, J. A novel composite sling for the Treatment of Stress Urinary Incontinence: First Clinical Experience. Presented June 22, 2001, Milan Italy, XXIII International Congress of the European Hernia Society
Bonnet, P. Transobturator vaginal tape inside out for the surgical treatment of female stress urinary incontinence: anatomical considerations. <i>J Urol</i> 2005; 173: 1223-1228
Boukerro. Objective analysis of mechanical resistance of tension-free devices. <i>Eur J Obstet Gynecol Reprod Biol</i> 124 (2006) 240-245
Boukerrou M, et al. Study of the biomechanical properties of synthetic mesh implanted in vivo. <i>Eur J Obstet Gynecol Reprod Biol</i> (2007) 134:262-267
Brennand, E. Twelve-month outcomes following midurethral sling procedures for stress incontinence: impact of obesity. <i>BJOG</i> 2015; 122: 1705-1712
Bringman S, et al. Hernia repair: The search for ideal meshes. <i>Hernia</i> (2010) 14:81-87.
Brown BN, et al. Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque. <i>American Journal of Obstetrics and Gynecology</i> (2015), doi:10.1016/j.ajog.2015.08.002.
Brubaker, Zimmern. (E-SISTEr 5 yr) [Pop 482] Adverse events over two years after retropubic or transobturator midurethral sling surgery: Findings from the trial of midurethral slings (TOMUS) Study. <i>Am J Obstet Gynecol</i> 2011;205:498e.1-6
Bryans, F. Marlex gauze hammock sling operation with Cooper's ligament attachment in the management of recurrent urinary stress incontinence. <i>Am J Obstet Gynecol</i> 1979; 133: 292-294

## Medical Literature

Bury. Five-year results of a randomized clinical trial comparing a polypropylene mesh with a poliglecaprone and polypropylene composite mesh for inguinal hernioplasty. Herina DOI 10.1007/s10029-012-0916-3
Byung. [pop 151, 6 mo fu] Changes in sexual function after mid-urethral tape sling operations for stress urinary incontinence in Korean women. Korean Journal of Urology Vol. 50 No 9:908-915 September 2009
Cadish, L. Preoperative vaginal estrogen and midurethral sling exposure: a retrospective cohort study. Int Urogynecol J 2016; 27: 413-417
Cammu, H. Dramatic increase (1997-2007) in the number of procedures for stress urinary incontinence in Belgium. Int Urogynecol J 2010; 21: 1511-1515
Canel, V. Postoperative groin pain and success rates following transobturator midurethral sling placement: TVT Abbrevio® system versus TVT™ obturator system. Int Urogynecol J 2015; Epub Ahead of Print
Capobianco, G. TVT-Abbrevio: efficacy and two years follow-up for the treatment of stress urinary incontinence. Clin Exp Obstet Gynecol 2014; 41(4): 445-447
Carbone JM, Kavalier E, Hu JC, Raz S. Pubovaginal sling using cadaveric fascia and bone anchors: disappointing early results. J Urol. 2001 May;165(5):1605-11.
Cassidenti A. The crushing of innovation for treating female pelvic floor disorders: A Story of "Lead or be Led." OBG Management 2016; 28(4): 9-14
Cavkaytar, S. Effects of Horizontal vs. Vertical Vaginal Cuff Closure Techniques on Vagina Length After Vaginal Hysterectomy: A Prospective Randomized Study. Journal of Minimally Invasive Gynecology 2014; 21(5): 884-7
Cayan, F. Sexual function after surgery for stress urinary incontinence: vaginal sling versus Burch colposuspension. Arch Gynecol Obstet 2008; 277: 31-36
Celebi. [Pop 563, 5 yrs fu] Results of the TVT procedure for treatment of female SUI: a 5 year follow-up study; Arch Gynecol Obstet (2009) 279:463-467
Chaikin, Blaivas. Pubovaginal fascial sling for all types of SUI Long-term analysis. J Urol, Vol. 160, 1312-1316 Oct. 1998
Chaikin, Blaivas. Results of pubovaginal sling for stress incontinence - a prospective comparison of 4 instruments for outcome analysis. J Urol Vol. 162, 1670-1673, November 1999
Chaliha. Complications of surgery for genuine stress incontinence. British Journal of Obstetrics and Gynaecology 1999; 106: 1238-1245
Chapple, Zimmern, et al. Mesh sling in an era of uncertainty. Lessons learned and the way forward. European Urology 64(2013) 525-529.
Chen, H. Efficacy and complication of TVT procedure and TVT-O procedure in treatment of female stress urinary incontinence. Journal of Shanghai Jiaotong University Medical Science 2012; 32(4): 412-415
Chen, Ridgeway, Paraiso. Biologic Grafts and Synthetic Meshes in Pelvic Reconstructive Surgery. Clinical Obstetrics and Gynecology (2007); 50(2): 383-411
Cheng D. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. Eur J of Obstet Gynecol Reprod Biol 161 (2012) 228-231
Chermansky, C. Role of pelvic floor in lower urinary tract function. Autonomic Neuroscience Basic and Clinical 2015; <a href="http://dx.doi.org/10.1016/j.autneu.2015.06.003">http://dx.doi.org/10.1016/j.autneu.2015.06.003</a>
Cheung, R. Inside-out versus outside-in transobturator tension-free vaginal tape: A 5-year prospective comparative study. Int J Urol 2014; 21: 74-80
Chichowski. Sexual Abuse History and Pelvic Floor Disorders in Women <i>South Med J.</i> 2013 Dec; 106(12): 675-678

## John Wagner Materials List

## Medical Literature

Choe JM, Bell T. Genetic material is present in cadaveric dermis and cadaveric fascia lata. J Urol. 2001 Jul;166(1):122-4.
Choe, J. Ch. 33 The Use of Synthetic Materials in Pubovaginal Sling. Bladder Disease: Research Concepts and Clinical Applications. Edited by A. ATala and D. Slade, Kluwer Academic/Plenum Publishers; 2003: 481-492
Christensen, H. Long-term Results of the Stamey Bladder-Neck Suspension Procedure and of the Burch Colposuspension. Scand J Urol Nephrol 1997; 31: 349-353
Christofi, N. Which procedure for incontinence? Journal of the British Menopause Society 2005; 11(1): 23-27
Chughtai B, et al. Association between the amount of vaginal mesh used with mesh erosions and repeated surgery after repairing pelvic organ prolapse and stress urinary incontinence. JAMA Surg (2016) doi: 10.1001/jamasurg.2016.4200.
Chughtai BI, et al. [SUFU Paper 35] Long term synthetic effects of vaginal mesh: seeking the truth. Female Pelvic Med Reconstr Surgery (2016); 22(5) (Suppl 1): S16-S17
Chughtai, Anger, et al. [AUGS Abs 35] Long term systemic effects of vaginal mesh: seeking the truth. Female Pelvic Med Reconstr Surg (2016); 22(5): S16-S17
Chughtai, Anger, et al. [SUFU Abs Podium 22] Is vaginal mesh a stimulus of autoimmune disease? (2017)
Chughtai, Anger, et al. [SUFU Abs Poster NM96] Transvaginal mesh is not associated with carcinogenesis. (2017)
Chughtai, B. Midurethral Sling is the dominant procedure for Female Stress Urinary Incontinence: Analysis of Case Logs From Certifying American Urologists. Urology 2013; 82(6): 1267-71
Chughtai. Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: population based cohort study; BMJ 2015;350:h2685
Chung, M. Comparison of Laparoscopic Burch and Tension-free Vaginal Tape in Treating Stress Urinary Incontinence in Obese Patients. JSLS 2002; 6: 17-21
Clave A, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J (2009).
Clave. Polypropylene as a reinforcement in pelvic surgery is not inert comparative analysis of 100 explants. Int Urogynecol J (2010) 21:261-270
Clemons. Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members' use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery. Female Pelvic Med Reconstr Surg 2013;19:191-198
Coady D. Chronic sexual pain. A layered guide to evaluation. Contemporary Ob/Gyn, September 2015, pp. 18-28.
Cobb WS, et al. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation, Vol 12, No 1 (March), 2005: pp69-69.
Cobb, Carbonell. Open Retromuscular Mesh Repair of Complex Incisional Hernia: Predictors of Wound Events and Recurrence. J Am Coll Surg 2015; 220:606-616
Cobb, Heniford, Kercher, et al. Textile Analysis of Heavy Weight, Mid-Weight, and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model. Journal of Surgical Research 136, 1-7 (2006)
Cobb. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation, Vol. 12, No. 1 (March), 2005: pp 63-69
Coda A, et al. Classification of prosthetics used in hernia repair based on weight and biomaterial. Hernia (2012) 16:9-20.
Coda, Bendavid. Structural alterations of prosthetic meshes in humans. Hernia (2003) 7:29-34

**Medical Literature**

Coelho, S. Female pelvic organ prolapse using pessaries: systematic review. <i>Int Urogynecol J</i> 2016; Epub ahead of print
Collinet P. et al. The Safety of the Inside-Out Transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. <i>Int Urogynecol J</i> (2008) 19:711-715
Comprehensive Review Course in Female Pelvic Medicine and Reconstructive Surgery- Master Suggested Readings List. Jan. 2013
Conze, J. New Polymer for Intra-Abdominal Meshes - PVDF Copolymer. <i>J Biomed Mater Res B Appl Biomater</i> 2008; 87(2): 321-8
Conze, Klinge, et al. Polypropylene in the intra-abdominal position Influence of pore size and surface area. <i>Hernia</i> (2004) 8:365-372.
Cornu, J. Midterm prospective evaluation of TVT-Secur Reveals High Failure Rate. <i>European Urology</i> 2010; 58: 157-161
Corona, R. Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy. <i>Journal of Minimally Invasive Gynecology</i> 2008; 15: 262-267
Cosson. Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? <i>Int Urogynecol J</i> (2003) 14:169-178
Costantini. [Pop 87, median 100 mos fu] Long-term efficacy of the trans-obturator and retropubic MUS for SUI: update from a randomized clinical trial; <i>World J Urol</i> , DOI 10.1007/s00345-015-1651-z, 2015
Costello CR, et al. Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient. <i>Surgical Innovation</i> 2007; 14(3): 168-176.
Cox A, Herschorn S, Lee L. Surgical management of female SUI: is there a gold standard? <i>Nat Rev Urol</i> 2013; 10(2):78-89.
Cresswell J, et al. [pop 118, mean 6.6 yrs fu] Long-term evaluation of tension-free vaginal tape (TVT) outcomes for a UK Surgeon: Objective assessment and patient satisfaction questionnaires. <i>British Journal of Medical and Surgical Urology</i> (2008) 1, 58-62.
Daneshgari, F. Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials. <i>Journal of Urology</i> 2008; 180: 1890-1897
Dati, S. M432 Single-Incision minisling (AJUST) vs. Obturator tension-free vaginal shortened tape (TVT-Abbrevio) in surgical management of female stress urinary incontinence. <i>International Journal of Gynecology &amp; Obstetrics</i> 2012; 119S3: S670
Davila, G. Pelvic Floor Dysfunction Management Practice Patterns: A Survey of Members of the International Urogynecological Association. <i>Int Urogynecol J</i> 2002; 13: 319-325
de Leval J. Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence. Transobturator Vaginal Tape Inside-Out. <i>European Urology</i> 44 (2003) 724-730.
de Leval, J. The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial. <i>Int Urogynecol J</i> 2011; 22:145-156
De Souza, A. Sexual Function following retropubic TVT and transobturator Monarc sling in women with intrinsic sphincter deficiency: a multicenter prospective study. <i>Int Urogynecol J</i> 2012; 23: 153-158
de Tayrac R and Letouzey V. Basic Science and Clinical Aspects of Mesh Infection in Pelvic Floor Reconstructive Surgery. <i>Int Urogynecol J</i> (2011), doi 10.1007/s00192-011-1405-4
Dean, N. Laparoscopic colposuspension and tension-free vaginal tape: a systematic review. <i>BJOG</i> 2006; 113: 1345-1353

**Medical Literature**

Debodinance, P. Trans-obturator urethral sling for surgical correction of female stress urinary incontinence: outside-in (Monarc®) versus inside-out (TVT-O®). Are both ways Safe? J Gynecol Obstet Biol Reprod 2006; 35: 571-577
Debodinance, P. Trans-obturator urethral sling for the surgical correction of female stress urinary incontinence: Outside-in (Monarc®) versus inside-out (TVT-O®) Are the two ways reassuring? Eur J Obstet Gynecol Reprod Biol 2007; 133: 232-238
Debodinance, P. TVT Secur™ Prospective Study and Follow Up to 1 year about 150 patients. Int Urogynecol J 2008; 19(Suppl 1): S11-12
Delmas - Ltrs to editor Re. de Leval's -Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. (2004)
Delorme E, et al. Transobturator tape (Uratape). A new minimally-invasive procedure to treat female urinary incontinence. European Urology 45 (2004) 203-207.
Delorme E. Transobturator urethral suspension. Mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2003;44:724-30
Delorme E. Trans-obturator tape: a mini invasive procedure for the treatment of female stress urinary incontinence. Progres en Urologie (Progress in Urology) (2001), II, 1306-1313
Demirci F, et al. Long-term results of Burch colposuspension. Gynecol Obstet Invest 2001; 51:243-247
Demirci, F. Comparison of pubovaginal sling and burch colposuspension procedures in type I/II genuine stress incontinence. Arch Gynecol Obstet 2001; 265: 190-194
Deng, Raz. Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported? Neurology and Urodynamics 26:46-52 (2007)
Deng. Risk factors for mesh erosion after female pelvic floor reconstructive surgery: a systemic review and meta-analysis BJU Int 2015 doi:10.1111/bju.13158
Denis. Pelvic Organ Prolapse Treatment by the Vaginal Route Using a Vypro Composite Mesh_ Preliminary results about 106 cases
Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006) 17:S16-S25.
Deprest. Synthetic and biodegradable prostheses in pelvic floor surgery. International Congress Series 1279 (2005) 387-397
Dhingra, C. Urogynecological Causes of Pain and the Effect of Pain on Sexual Function in Women. Female Pelvic Med Reconstr Surg 2012; 18: 259-267
Di Biase, M. Management of stress urinary incontinence. Seminars in Colon and Rectal Surgery 2016; 27: 46-50
Diamond MP and Freeman ML. Clinical implications of postsurgical adhesions. Human Reproduction Update (2001); 7(6): 567-576.
Dietz HP, et al. [Pop 68, median 1.6 yrs fu] Does the Tension-Free Vaginal tape stay Where you Put It? Am J Obstet Gynecol 2003; 188:950-3
Dietz HP, et al. Mechanical properties of urogynecologic implant materials. Int Urogynecol J (2003) 14:239-243.
Dietz. Mesh contraction: myth or reality? Am J Obstet Gynecol (2011); 204:173.e1-4.
Dmochowski, et al. Slings: Autologous, Biologic, Synthetic, and Midurethral. Chapter 273 in Wein 10th ed (2011)
Dmochowski, R et al. Update of AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence. J Urol . Vol 183, 1906-1914, May 2010
Dmochowski, R. One Year Results from a World-wide Registry of TVT-SECUR™ in Women with Stress Urinary Incontinence, Paper Submission 09-AB-97051-AUA. J Urol (2009);181(4)(Suppl)

## John Wagner Materials List

## Medical Literature

Drutz H. IUGA guidelines for training in female pelvic medicine and reconstructive pelvic surgery (FPM-RPS). Updated Guidelines 2010. Int Urogynecol K=J 2010; 21: 1445-1453.
Drutz HP. Updated IUGA guidelines for training in female pelvic medicine and reconstructive surgery (FPM-RPS). Int Urogynecol J (2010) 21:1445-1453.
Drutz, H. IUGA guidelines for training in female pelvic medicine and reconstructive pelvic surgery (FPM-RPS). Updated Guidelines 2010. Int Urogynecol K=J 2010; 21: 1445-1453.
Duckett, J. Groin pain after a tension-free vaginal tape or similar suburethral sling: management strategies. BJU International 2005; 95: 95-97
Duckett, J. Pain after suburethral sling insertion for urinary stress incontinence. Int Urogynecol J 2013; 24: 195-201
Dunn GE. Changed women. The long-term impact of vaginal mesh complications. Female Pelvic Med. Reconstr Surg 2014; 20:131-136
Dwyer PL and Riss P. Synthetic mesh in plevic reconstructive surgery: an ongoing saga. Int Urogynecol J (2016) 27:1287-1288.
Dwyer, N. An update on slings. Curr Opin Urol 2005; 15: 244-249
Dyrkorn OA, Kulseng-Hanssen S, Sandvik L. TVT compared with TVT-O and TOT: Results from the Norwegian National Incontinence Registry; Int Urogynecol J (2010) 21:1321-1326.
Eickmeyer, S. Pelvic Floor Disorders. Chapter 38 in Braddom's Physical Medicine & Rehabilitation Fifth Edition ISBN: 978-0-323-28046-4
El-Din Shwki, H. The Role of Trans-obturator Vaginal Tape (TVT-O) and some Traditional Surgical interventions in the management of female genuine stress urinary incontinence - randomized controlled trial. International Journal of Gynecology & Obstetrics 2012; 119S3: S337
Elyasi, F. Sexual Dysfunction in Women with Type 2 Diabetes Mellitus. Iran J Med Sci 2015; 40(3): 206-213
Endo, M. Mesh contraction: in vivo documentation of changes in apparent surface area utilizing meshes visible on magnetic resonance imaging in the rabbit abdominal wall model. Int Urogynecol J 2014; 25(6): 737-43
Ercan, O. Comparison of postoperative vaginal length and sexual function after abdominal, vaginal, and laparoscopic hysterectomy. International Journal of Gynecology and Obstetrics 2016; 132: 39-41
Eriksen, B. Long-term effectiveness of the burch colposuspension in Female Urinary Stress Incontinence. Acta Obstet Gynecol Scand 1990; 69: 45-50
Fabian, G. Vaginal excision of the sub-urethral sling: analysis of indications, safety and outcome. Arch Med Sci 2015; 11(5): 982-988
Falconer C. Clinical Outcome and Changes in Connective Tissue Metabolism After Intravaginal Slingplasty in Stress Incontinence Women. Int Urogynecol J 1996; 7: 133-137
Falconer. Influence of Different Sling Materials on Connective Tissue Metabolism in SUI Women; Int Urogynecol J (2001) (Suppl 2):S19 S23
Fan, Y. Incontinence-specific quality of life measures used in trials of sling procedures for female stress urinary incontinence: a meta-analysis. Int Urol Nephrol 2015; Epub Ahead of Print
Feiner B & Maher C. Vaginal Mesh Contraction Definition Clinical Presentation and Management. Obstet Gynecol (2010); 115:325-330.
Feola A, et al. Deterioration in biomechanical properties of the vagina following implantation of a high-stiffness prolapse mesh. BJOG 2013; 120:224-332.
Ferrero, S. Deep dyspareunia: causes, treatments, and results. Current Opinion in Obstetrics and Gyencology 2008; 20: 394-399

## Medical Literature

FitzGerald MP, Edwards SR, Fenner D. Medium-term follow-up on use of freeze-dried, irradiated donor fascia for sacrocolpopexy and sling procedures. Int Urogynecol J Pelvic Floor Dysfunct. 2004 Jul-Aug;15(4):238-42.
Fitzgerald MP, Mollenhauer J, Brubaker L. Failure of allograft suburethral slings. BJU Int. 1999 Nov;84(7):785-8.
Fitzgerald MP, Mollenhauer J, Brubaker L. The antigenicity of fascia lata allografts. BJU Int. 2000 Nov;86(7):826-8.
Fitzgerald, M. Failure of allograft suburethral slings. BJU International 1999; 84: 785-788
Fokaefs, E. Experimental evaluation of free versus pedicled Fascial Flaps for Sling Surgery of Urinary Stress Incontinence. J Urol 1997; 157: 1039-1043
Fong, E. Mid-urethral synthetic slings for female stress urinary incontinence. BJU Int 2010; 106(5): 596-608
Ford AA, et al. (Cochrane Review[FULL]) Mid-urethral sling operations for stress urinary incontinence in women. The Cochrane Library 2015, Issue 7
Ford. (Cochrane Review) [Abstract] Mid-urethral sling operations for stress urinary incontinence in women (review); The Cochrane Library 2015, Issue 7
Fortelny, R. Adverse effects of polyvinylidene fluoride-coated polypropylene mesh after for laparoscopic intraperitoneal onlay repair of incisional hernia. British Journal of Surgery 2010; 97: 1140-1145
Foxman B. Epidemiology of Urinary Tract Infections: Incidence, Morbidity, and Economic Costs. Am J Med 2002; 113(1A):5S-13S.
Francis, W. Dyspareunia Following Vaginal Operations. The Journal of Obstetrics and Gynaecology of the British Commonwealth 1961; 68(1): 1-10
Fultz, N. Burden of stress urinary incontinence for community-dwelling women. Am J Obstet Gynecol 2003; 189: 1275-82
Funk, M. Trends in the Surgical Management of Stress Urinary Incontinence. Obstet Gynecol 2012; 119(4): 845-851
Gagnon, L. Better Short-term Outcomes with The U-Method compared with the Hammock Technique for the Implantation of TVT-SECUR Under Local Anesthesia. Urology 2010; 75: 1060-1064
Galloway, N. The Complications of Colposuspension. British Journal of Urology 1987; 60: 122-124
Gandhi S, et al. TVT versus SPARC - Comparison of Outcomes for two midurethral tape procedures. Int Urogynecol J (2006) 17:125-130
Garcia, S. Complications of Polypropylene Mesh for the Treatment of Female Pelvic Floor Disorders. Neurologic and Urodinamical Urology Arch. Esp. Urol. 2011; 64(7): 620-628
Garcia-Urena MA, et al. Differences in polypropylene shrinkage depending on mesh position in experimental study. Am J Surg (2007); 197: 538-542.
Gauruder-Burmester A, et al. Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse. Int Urogynecol J (2007) 18:1059-1064.
Gehrich, A. Risk of postoperative urinary tract infections following midurethral sling operations in women undergoing hysterectomy. Int Urogynecol J 2015; Epub Ahead of Print
Gerstenbluth. [case report] Simultaneous urethral erosion of TVT and woven polyester pubovaginal sling. J Urol Vol. 170, 525-526, August 2003
Ghoneim, G. Female pelvic medicine and reconstructive surgery practice patterns: IUGA member survey. Int Urogynecol J 2015; 26(10): 1489-94
Gilbert AI, et al. Ch. 9 Polypropylene. The Standard of Mesh Materials. Meshes - Benefits and Risks (2004)
Glatt, A. The Prevalence of Dyspareunia. Obstet Gynecol 1990; 75 (3)(Part 1): 433-436

# Medical Literature

Glavind, K. Incidence and treatment of postoperative voiding dysfunction after the tension-free vaginal tape procedure. <i>Int Urogynecol J</i> 2015; 26: 1657-1660
Gleason, Sung, Richter. Outcomes of MUS procedures in women with mixed urinary incontinence; <i>Int Urogynecol J</i> (2015) 26:715-721
Godazandeh, G. Laparoscopic Repair of Morgagni Hernia Using Polyvinylidene Fluoride (PVDF) Mesh. <i>Middle East J. Dig Dis</i> 2012; 4:232-235
Goldman, HW. Complications of Female Incontinence & Pelvic Reconstructive Surgery. <i>Current Clinical Urology</i> 2013.
Golomb, J. Management of urethral erosion caused by a pubovaginal fascial sling. <i>Urology</i> 2001; 57: 159-160
Gomelsky, A. Midurethral sling: is there an optimal choice? <i>Curr Opin Urol</i> 2016; 26: 000-000 DOI: 10.1097/MOU.0000000000000282
Gomelsky. (Ann Long-Term Care) Urinary incontinence in the elderly female. <i>Annals of Long-Term Care: Clinical Care and Aging</i> 2009; 17[10]:41-45
Goretzlehner, U. PVDF as an implant material in urogynaecology. <i>BIOMaterialien</i> 2007; 8(S1): 28-29
Gorlero, F. A new technique for surgical treatment of stress urinary incontinence: the TVT-Secur. <i>Minerva Ginecol</i> 2008; 60: 459-68
Greer, W. Obesity and Pelvic Floor Disorders. <i>Obstet Gynecol</i> 2008; 112: 341-9
Groutz A, Rosen G, Cohen A, Gold R, Lessing JB, Gordon D. [Pop 52, 10 yr fu] Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. <i>J Minim Invasive Gynecol</i> (2011) 18:726-729
Groutz, A. Long-Term Outcome of Transobturator Tension-Free Vaginal Tape: Efficacy and Risk Factors for Surgical Failure. <i>Journal of Women's Health</i> 2011; 20(10): 1525-1528
Groutz, Blaivas. Pubovaginal sling surgery for simple SUI - analysis by an outcome score. <i>The Journal of Urology</i> Vol. 165, 1597-1600, May 2001
Groutz. [Pop 52, 10 yr fu] Ten-Year Subjective Outcome Results of the Retropubic Tension-Free Vaginal Tape for Treatment of SUI; <i>Journal of Minimally Invasive Gynecology</i> , Vol.18, No 6, November/December 2011
Haferkamp.
Halder, G. Botox with Physical Therapy for Myofascial Pelvic Pain. Presentation Number: Poster 193. <i>Female Pelvic Medicine &amp; Reconstructive Surgery</i> 2015; 21(5)(Suppl 1): S143
Hamer MA, et al., One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. <i>Int Urogynecol J</i> 2013;24:223-229.
Hammad. Erosions and Urinary Retention Following Polypropylene Synthetic Sling. <i>Australasian Survey. Eur Urol</i> 47 (2005) 641-647
Hampel. Prevalence and natural history of female incontinence. <i>Eur Urol</i> . 1997;32 Suppl 2:3-12
Hampel. Understanding the burden of stress urinary incontinence in Europe: a qualitative review of the literature <i>Eur Urol</i> . 2004 Jul;46(1):15-27
Han JY, et al. Efficacy of TVT-SECUR and factors affecting cure of female stress urinary incontinence: 3-year follow-up. <i>Int Urogynecol J</i> 2012 Dec;23(12):1721-1726.
Han J-Y, Park J, Choo M-S. [Pop 88, 12 yr fu] Long-term durability, functional outcomes, and factors associated with surgical failure of tension-free vaginal tape procedure. <i>Int Urol Nephrol</i> (2014) 46:1921-1927
Hansen, Gradel. [Danish Registry] Reoperation for urinary incontinence-a nationwide cohort study, 1998 thru 2007; <i>Am J Obstet Gynecol</i> 2016;214:263.e1-8
Hartmann & Sarton. Chronic pelvic floor dysfunction. <i>Best Pract Res Clin Obstet Gynaecol</i> . 2014 Oct;28(7):977-90

## Medical Literature

Hathaway JK, Choe JM. Intact genetic material is present in commercially processed cadaver allografts used for pubovaginal slings. J Urol. 2002 Sep;168(3):1040-3. PubMed PMID: 12187218.
Haug JD. Physicians preferences for information sources - a meta-analytical study. Bull Med Libr Assoc 85(3), July 1997.
Haylen BT, et al. Recurrent urinary tract infections in women with symptoms of pelvic floor dysfunction. Int Urogynecol J (2009) 20:897-842.
Hazell L. and Shakir SAW. Under-reporting of adverse drug reactions. Drug Safety 2006; 29(5):385-396.
Heinonen P. [Pop 191, mean 10.5 yrs fu] Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome. Int J Urol 2012; 19:1003-1009
Heinz. The Reaction of Formaldehyde with Proteins - Formalin Reaction. From the Western Regional Research Laboratory. September 7, 1948
Heise CP and Starling JR. Mesh inguinodynia: A new clinical syndrome after inguinal herniorrhaphy? J Am Coll Surg (1998); 187: 514-518.
Herbertsson. Surgical results and urodynamic studies 10 years after retropubic colpourethrocystopexy. Acte Obstet Gynecol Scand 1993; 72:298-301
Hermieu. Les bandelettes sous-uretrales synthetiques dans le traitement de l'incontinence urinaire d'effort feminine. Peoples en Urologie (2003), 13, 636-647
Hijaz A. Female Urology and Urodynamics at AUA 2014. AUA News . October 2014: 11-13
Hill, Barber. Histopathology of excised midurethral sling mesh. Int Urogynecol J (2015) 26:591-595
Hilton, P. The "learning curve" for retropubic mid-urethral sling procedures: a retrospective cohort study. Int Urogynecol J 2016; 27: 565-570
Hinoul P, et al. A Randomized, Controlled Trial Comparing an Innovative Single Incision Sling With an Established Transobturator Sling to Treat Female stress urinary incontinence. J Urol 2011; 185:1356-1362.
Hinoul, P. An anatomic comparison of the original versus a modified inside-out transobturator procedure. Int Urogynecol J 2011; 22: 997-1004
Hinoul, P. An Anatomic Comparison of the Traditional TVT-O Versus a modified TVT-O Procedure. Int Urogynecol J 2011; 22 (Suppl 2): S1190-1191
Hinoul, P. TVT Obturator system versus TVT Secur: a randomized controlled trial, short term results. Int Urogynecol J 2009; 20 (Suppl 2): S213
Holmgren S, Nilsson. [Pop 760, 8 yr fu] Long-Term Results with Tension-Free Vaginal Tape on Mixed and Stress Urinary Incontinence. Obstetrics & Gynecology; Vol. 106, No. 1, July 2005
Holmgren, C. Frequency of de novo urgency in 463 women who had undergone the tension-free vaginal tape (TVT) procedure for genuine stress urinary incontinence - A Long-Term Follow-up. Eur J Obstet Gynecol Reprod Biol 2007; 132: 121-125
Holmgren. Quality of life after TVT surgery for female stress incontinence; Scandinavian Journal of Urology and Nephrology, 2006; 40: 131-137
Hota, L. TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. Female Pelvic Med Reconstr Surg 2012; 18:41-45
Houwert RM, et al. TVT-O versus Monarc after a 2-4-year follow-up: a prospective comparative study. Int Urogynecol J (2009) 20:1327-1333.
Houwert, R. Perspectives by patients and physicians on outcomes of mid-urethral sling surgery. Int Urogynecol J 2010; 21: 415-421
Hu, T. Costs of Urinary incontinence and overactive bladder in the United States: A comparative Study. Urology 2004; 63: 461-465

## Medical Literature

Huang YH, Lin AT, Chen KK, Pan CC, Chang LS. High failure rate using allograft fascia lata in pubovaginal sling surgery for female stress urinary incontinence. Urology. 2001 Dec;58(6):943-6.
Huang, Y. High Failure Rate using Allograft Fascia Lata in Pubovaginal sling surgery for Female Stress Urinary Incontinence. Urology 2001; 58: 943-946
Hubka, P. Anatomical study of position of the TVT-O to the obturator nerve influenced by the position of the legs during the procedure: based upon findings at formalin-embalmed and fresh-frozen bodies. Arch Gynecol Obstet 2011; 284: 901-905
Hubka, P. TVT Abbrevio: cadaveric study of tape position in foramen obturatum and adductor region. Int Urogynecol J 2016; Epub Ahead of Print
Huser, M. [OP 106] Prospective Randomized Comparison of the Trans-obturator mid-urethral sling and the single-incision sling in women with stress urinary incontinence: One-year follow-up study. Int Urogynecol J 2015; 26(Suppl1): S135-136
Iakovlev, Mekel, Blaivas. [ICS Abs 228] Pathological findings of transvaginal polypropylene slings explanted for late complications: mesh is not inert.(2014)
Iglesia, C. The Use of mesh in Gynecologic Surgery. Int Urogynecol J 1997; 8: 105-115
Iliev VN and Andova IT. Minimally invasive surgery for stress urinary incontinence - mesh complications. Med. Sci. 2, 2014.
Imel A, et al. In vivo oxidative degradation of polypropylene pelvic mesh. Biomaterials 73 (2015) 131-141.
Ingber, M. Retropubic Synthetic Midurethral Slings: Techniques and Outcomes. Current Urology Reports 2009; 10: 375-383
Irwin, D. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. Eur Urol 2006; 50: 1306-1315
Jackson, S. Stress urinary incontinence: new management options. Current Medical Research and Opinion 2005; 21(10): 1669-1675
Jacquetin & Cosson. Complications of vaginal mesh Our experience. (2009)
Jain, P. Effectiveness of midurethral slings in mixed urinary incontinence: a systematic review and meta-analysis. Int Urogynecol J DOI: 10.1007/s00192-011-1406-3
Jamieson, D. The Prevalence of dysmenorrhea, dyspareunia, pelvic pain, and irritable bowel syndrome in primary care practices. Obstet Gynecol 1996; 87(1): 55-58
Jarnagin, B. Postoperative ureteral obstruction after confirmed ureteral patency: a case report. Int Urogynecol J 2004; 15: 356-357
Jelovsek J, et al. (BJOG) [Pop 72, mean 62 mos fu] Randomised trial of laparoscopic Burch colposuspension versus TVT: long-term follow up; BJOG 2008; 115:219-225
Jelovsek, J. Predicting Risk of Urinary Incontinence and Adverse Events After Midurethral Sling Surgery in Women. Obstet Gynecol 2016; 127: 330-40
Jeon. [pop 253] Comparison of the treatment outcome of pubovaginal sling, TVT, and TVT-O for SUI with intrinsic sphincter deficiency; American Journal of Obstetrics & Gynecology; July 2008; Volume 199, Number 1
Jeppson, S. [NON-ORAL POSTER 31] Effect of TVT-O Abbrevio on Post-Operative Groin Pain Journal of Minimally Invasive Gynecology 2014; 21: S27-S28
Jern. [pop 144, 62 at 7 yr fu] Long-Term Follow-up of the TVT Procedure for Treating Female SUI; Journal of Urology Volume 181, Number 4; April 2009
Jha, S. Surgical Management of Stress Urinary Incontinence A Questionnaire Based Survey. Eur Urol 2005; 47: 648-652
Jha. (see 2011 full article) IUGA Abs 213 - Impact of incontinence surgery on sexual function: a systematic review and meta-analysis. Int Urogynecol J (2010) 21 (Suppl 1):S1-S428

## Medical Literature

Jha. [Meta-analysis] Impact of incontinence surgery on sexual function. A systematic review and meta-analysis. J Sex Med 2012;9:34-43
Jha. Prolapse or incontinence - what affects sexual function the most? Int Urogynecol J (2016) 27:607-611
Jonsson Funk M. Sling Revision/ Removal for Mesh Erosion and Urinary Retention: Long-Term Risk and Predictors. Am J Obstet Gynecol. 2013; 208(1): 73.e1-73.e7
Kalichman, L. Association between fibromyalgia and sexual dysfunction in women. Clin Rheumatol 2009; 28: 365-369
Kammerer-Doak DN, Rogers RG, Bellar B. Vaginal erosion of cadaveric fascia lata following abdominal sacrocolpopexy and suburethral sling urethropexy. Int Urogynecol J Pelvic Floor Dysfunct. 2002;13(2):106-9; discussion 109.
Kaplan, S. Comparison of Fascial and Vaginal Wall Slings in The Management of Intrinsic Sphincter Deficiency. Urology 1996; 47: 885-889
Karaman, U. [AUA ABS PS28-07] The impact of obesity on outcomes after retropubic midurethral sling for female stress urinary incontinence. 2015
Karim, N. Review on midurethral sling procedures for stress urinary incontinence. Gynecology and Minimally Invasive Therapy 2015; 4: 33-36
Karlovsy M. Synthetic Biomaterials for Pelvic Floor Reconstruction. Current Urology Report 2005; 6:376-384
Karmakar, D. Long-Term Outcomes (8-Years) From the Prospective Randomized Control Trial of Trans-obturator tapes for stress incontinence in women (The ETOT Study). Int Urogynecol J 2015; 26 (Suppl 1): S74-75
Karram, M. An Evaluation of the Gynecare TVT Secur* System (Tension-free Support for Incontinence) for the treatment of Stress Urinary Incontinence. Int Urogynecol J 2007; 18(Suppl 1): S3
Karram, M. Powerpoint Early Clinical Experience of Gynecare TVT Secur* System for treatment of Stress Urinary Incontinence.
Karram, M. When and how to place an autologous rectus fascia pubovaginal sling. OBG Management 2012; 24(11): 24-33
Karram. Complications and Untowards Effects of the TVT Procedure. Obstet Gynecol 2003; 101:929-32
Kaufman Y , et al. Age and sexual activity are risk factors for mesh exposure following transvaginal mesh repair. Int Urogynecol J (2011) 22: 307-313
Kavvadias, Klinge. Ch. 56 Alloplastic Implants for the Treatment of SUI and Pelvic Organ Prolapse. Hernia Repair Sequelae Chapter 56 pp. 440-444
Kenton K, Zyczynski H, Sirls LT, Richter HE, et al. (TOMUS published) 5-Year Longitudinal Followup after Retropubic and Transobturator Mid-urethral slings. J Urol 2015; 193: 203-210
Kenton KS, Richter H. Risk Factors Associated with Urge Incontinence after Continence Surgery. J Urol 2009 Dec: 182 (6):2805-2809
Kenton, K. Surgical Management of Stress Urinary Incontinence in Women: Bladder neck fascial sling procedures. UpToDate; 2015: 1-4
Kersey J. The gauze hammock sling operation in the treatment of stress incontinence. Br J Obstet Gynecol 1983; 90:945-949.
Khan. [Pop 162, median 10 yr fu] Long term follow-up of a multicentre randomised controlled trial comparing TVT, xenograft and autologous fascial slings for the treatment of SUI in women; doi:10.1111/bju.12851; 2014

# Medical Literature

Khandwala, S. Experience with TVT-SECUR sling for stress urinary incontinence: a 141-case analysis. <i>Int Urogynecol J</i> 2010; 21: 767-772
Khandwala, S. TVT-Secur in office sling procedure under local anesthesia: a prospective 2-year analysis. <i>Female Pelvic Med Reconstr Surg</i> 2012; 18: 233-238
King AB, Goldman HB. Current controversies regarding oncologic risk associated with polypropylene midurethral slings. <i>Curr Urol Rep</i> (2014) 15:453.
King, A. Prospective Evaluation of the Effect of Thigh Dissection for Removal of Transobturator Midurethral Slings on Refractory Thigh Pain. (Author's Manuscript) <i>J Urol</i> 2016; 10.1016/j.juro.2016.03.153
Kinn, A. Burch Colposuspension for Stress Urinary Incontinence. <i>Scand J Urol Nephrol</i> 1995; 29: 449-455
Kirby A. Midurethral slings: which should I choose and what is the evidence for use? <i>Curr Opin Obstet Gynecol</i> 2015; 27: 359-365
Kjohede, P. Long-Term Efficacy of Burch Colposuspension: a 14-year follow-up study. <i>Acta Obstet Gynecol Scand</i> 2005; 84: 767-772
Klinge, Klosterhalfen, Schumpelick. Shrinking of Polypropylene Mesh in vivo: an experimental study in dogs*. <i>Eur J Surg</i> 1998 164:965-969
Klinge. Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. <i>Eur J Surg</i> 1999; 165:665-673
Klinge. Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model. <i>Journal of Surgical Research</i> 103, 208-214 (2002)
Klinge. Polypropylene in the intra-abdominal position: Influence of pore size and surface area. <i>Hernia</i> (2004) 8:365-372
Klinge. [review-discussion] Advances in Urogynecology (discusses TVT). <i>Int J Fertil</i> 50[1]:18-23, 2005
Klink, C. Comparison of Long-Term Biocompatibility of PVDF and PP Meshes. <i>Journal of Investigative Surgery</i> 2011; 24: 292-299
Klosterhalfen B, Klinge U, Schumpelick V. Ch. 29 - Carcinogenicity of Implantable Biomaterials. <i>Ben David's Abdominal Wall Hernias</i> (2001)
Klosterhalfen B. Influence of implantation interval on the long-term biocompatibility of surgical mesh. <i>British Journal of Surgery</i> 2002; 89: 1043-1048
Klosterhalfen, Klinge, et al. Ch. 16 - Long-term inertness of meshes In <i>Meshes. Biomaterial-related FBR. IN Meshes-Benefits and Risks.</i> (2004)
Klosterhalfen, Klinge, Junge, et al. Ch. 24 - Foreign-body Carcinogenesis of Surgical Meshes. <i>Meshes- Benefits and Risks</i> (2004)
Klosterhalfen, Klinge. The lightweight and large porous mesh concept for hernia repair. <i>Expert Rev. med. Devices</i> 2(1), 103-117 (2005)
Klosterhalfen. Foreign-body Carcinogenesis of Surgical Meshes. <i>Meshes: Benefits and Risks. Chapter 24 pp.254-261</i>
Kobashi, K. Management of vaginal erosion of polypropylene mesh slings. <i>J Urol</i> 2003; 169: 2242-2243
Kobashi, K. Perioperative complications: The First 140 Polypropylene Pubovaginal Slings. <i>J Urol</i> 2003; 170: 1918-1921
Kokanali MK, et al. [Pop 1439] Risk factors for mesh erosion after vaginal sling procedures for urinary incontinence. <i>Eur J Obstet Gynecol</i> 2014; 177:146-150.
Komesu, Y. Epidemiology of mixed, stress, and urgency urinary incontinence in middle-aged/older women: the importance of incontinence history. <i>Int Urogynecol J</i> 2014; Epub Ahead of Print

# Medical Literature

Koo, Gormley. [AUA Abs MP81-05] Transvaginal Mesh in the Media Following the 2011 FDA Update
Koo, Gormley. [published] Transvaginal Mesh in the Media Following the 2011 US FDA Public Health Notification Update; Neurourology and Urodynamics DOI 10.1002/nau 2015
Krambeck, A. Time-Dependent Variations in Inflammation and Scar Formation of Six Different Pubovaginal Sling Materials in the Rabbit Model. Urology 2006; 67: 1105-1110
Krause H, et al. Biomechanical properties of raw meshes used in pelvic floor reconstruction. Int Urogynecol J (2008) 19:1677-1681.
Kuhn A, et al. [Pop 18, 3 mo fu] Sexual function after suburethral sling removal for dyspareunia. Surg Endosc (2009) 23:765-768
Kurien, A. EP13.17 TVT Abbrevio for management of female stress urinary incontinence: a prospective analysis over 22 months in a tertiary care hospital. BJOG 2014; 121(2): 235-236
Kurtz. Effects of reactive oxygen species on the physical properties of polypropylene surgical mesh at various concentrations: a model for inflammatory reaction as a cause for mesh embrittlement and failure. Surg Endosc doi 10.1007/s00464-015-4614-3
Kuuva N, Nilsson. [Pop 1455, 2 mo fu] A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 2002; 81: 72-77
Kuuva, Nilsson. [Pop 129, 6 yr fu] Long-term results of the TVT operation in an unselected group of 129 stress incontinent women; Acta Obstetrica et Gynecologica. 2006; 85: 482-487
Kuuva, Nilsson. [pop 51] TVT procedure. An effective minimally invasive operation for the treatment of recurrent SUI?; Gynecol Obstet Invest 2003;56:93-98
Lamvu, G. Vaginal Apex Resection: A Treatment Option for Vaginal Apex Pain. Obstet Gynecol 2004; 104: 1340-6
Langer. Long-Term (10-15 years) Follow-up after Burch Colposuspension for Urinary Stress Incontinence. Int Urogynecol J (2001) 12:323-327
Lapitan, Cody. [Summary Cochrane review] Open retropubic colposuspension for urinary incontinence in women (review). Cochrane Database of Systemic Reviews 2016 , Issue 2. Art. No.:CD002912
Lapitan. (Cochrane Rev) Open Retropubic Colposuspension Urinary Inc in Women Short Version Cochrane Review; Neurourology and Urodynamics 28:472-480 (2009)
Lapitan. Open Retropubic Colposuspension for urinary incontinence in women (Review) Reprint of Cochran review prepare and maintained by The Cochrane collaboration and published in The Cochrane Library 2012, Issue 6
Lathe P, Foon R, Tooze-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007;114:522-531.
Latthe PM, Singh P, Foon R, Tooze-Hobson P. [meta-analysis] Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials. BJU Int (2010) 106:68-76
Laumann, E. Sexual Dysfunction in the United States: Prevalence and Predictors. JAMA 1999; 281: 537-544
Laurikainen E, Valpas A, Aukee P, Kivelä A, Rinne K, Takala T, Nilsson CG. [Pop 254, 5 yr fu] Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. Eur Urol (2014) 65:1109-1114; <a href="http://dx.doi.org/10.1016/j.eururo.2014.01.031">http://dx.doi.org/10.1016/j.eururo.2014.01.031</a>
Laurikainen. Retropubic Compared with Transobturator Tape Placement in Treatment of Urinary Incontinence. A Randomized Controlled Trial; Obstetrics & Gynecology (2007) Vol. 109, No. 1, January 2007

**Medical Literature**

Lavelle, E. Stress Urinary Incontinence: Comparative Efficacy Trials. <i>Obstet Gynecol Clin N Am</i> 2016; 43: 45-57
Leanza, V. Comparison between three mini-sling surgical procedures and the traditional transobturator vaginal tape technique for female stress urinary incontinence. <i>G Chir</i> 2014; 35(314): 80-84
Leclerc. History of sexual and physical abuse in women with dyspareunia: association with pain, psychosocial adjustment, and sexual functioning. <i>J Sex Med</i> . 2010 Feb;7(2 Pt 2):971-80
Lee HN, et al. Tension-Free Vaginal Tape-SECUR Procedure for the Treatment of Female Stress Urinary Incontinence: 3-Year Follow-Up Results. <i>Low Urin Tract Symptoms</i> . 2015 Jan;7(1):9-16.
Lee K. [Pop 120, 1 yr fu] A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence 1-year followup. <i>J Urol</i> 2007; 177: 214-218
Lee, E. Midurethral slings for all stress incontinence: A urology Perspective. <i>Urol Clin N Am</i> 2012; 39: 299-310
Lee, K. A prospective multicenter randomized comparative study between the U- and H- Type Methods of the TVT SECUR procedure for the treatment of Female Stress Urinary Incontinence: 1-Year Follow-up. <i>European Urology</i> 2010; 57: 973-979
Lee. [Pop 141, 85.5 mo fu] Long-term outcome of the TVT procedure in female urinary incontinence: a 6 year follow-up; <i>Korean J Urol</i> 2010; 51:409-415
Letouzey V, et al. Ultrasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arms Trans Obturator Techniques to Bilateral Anterior Sacrospinous Ligament and Arcus Tendineus Suspension, at 1 Year Follow Up. <i>Int Urogynecol J</i> (2011)22 (Suppl 1): S151-S152.
Li B, Zhu L, Lang JH, Fan R, et al. [Pop 55, 7 yr fu] Long-term outcomes of the tension-free vaginal tape procedure for female stress urinary incontinence: 7-year follow-up in China. <i>J Minim Invasive Gynecol</i> . 2012 Mar-Apr;19(2):201-5.
Li. [Pop 55, 7 yr fu] Long-term outcomes of the TVT procedure for female SUI 7-year follow-up in China; <i>Journal of Minimally Invasive Gynecology</i> , Vol. 19, No. 2, March/April 2012
Liapis A, Bakas P, Creatsas G. [Pop 65, 5 & 7 yr fu] Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. <i>Int Urogynecol J Pelvic Floor Dysfunct</i> (2008) 19:1509-1512
Liapis A, Bakas P, Creatsas. Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. <i>European Journal of Obstetrics &amp; Gynecology and Reproductive Biology</i> 148 (2010) 199-201
Liapis, A. Monarc vs. TVT-O for the treatment of primary stress incontinence: a randomized study. <i>Int Urogynecol J</i> 2008; 19: 185-190
Liebert. Subcutaneous Implants of Polypropylene Filaments. <i>J Biomed Mater. Res</i> . Vol. 10 pp939-951 (1976)
Lim. [Pop 664] Do the Advantage slings work as well as the tension-free vaginal tapes? <i>Int. Urogynecol J</i> (2010) 21:1157-1162
Lin, A. In Vivo Tension sustained by Fascial Sling in Pubovaginal sling surgery for Female Stress Urinary Incontinence. <i>J Urol</i> 2005; 173: 894-897
Linder BJ, et al. Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. <i>Int Urogynecol J</i> (2016), doi 10.1007/s00192-016-2961-4
Linder, B. Predictors of vaginal mesh exposure after midurethral sling placement: a case - control study. <i>Int Urogynecol J</i> 2016; Epub Ahead of Print, DOI 10.1007/s00192-016-2947-2

## Medical Literature

Lindquist. [pop 44, mean 4.9 yr fu] Long-term follow-up of sexual function in women before and after TVT operation for stress urinary incontinence. <i>Int Urogynecol J</i> doi 10.1007/s00192-016-3004-x
Lo TS, et al. Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. <i>Urology</i> 63:671-675, 2004
Lohse, C. A Rare Complication with TVT: Vaginal Protusion of the Tape. <i>Int Urogynecol J</i> 2002; 13: 330-331
Long. (rev TOT v. TVT) Comp TVT & transobturator tape procedure for treatment of SUI; Current Opinion in Obstetrics and Gynecology 2009, 21:342-347
Lose, G. Voiding Difficulties After Colposuspension. <i>Obstet Gynecol</i> 1987; 69: 33-38
Lowenstein, L. Does Hysterectomy affect genital sensation? <i>Eur J Obstet Gynecol Reprod Biol</i> 2005; 119: 242-245
Lowenstein, L. Vulvar vestibulitis severity - assessment by sensory and pain testing modalities. <i>Pain</i> 2004; 107: 47-53
Lower AM, et al. Adhesion-related readmissions following gynaecological laparoscopy or laparotomy in Scotland: an epidemiological study of 24,046 patients. <i>Human Reproduction</i> (2004); 19(8): 1877-1885.
Lowman JK. Tobacco use is a risk factor for mesh erosion after abdominal sacral colpoperineopexy. <i>Am J. Obstet Gynecol</i> (May 2008) 198(5):561.
Lucas MG, et al. EAU Guidelines on Surgical Treatment of Urinary Incontinence. <i>Eur Urol</i> (2012) 62:1118-1129.
Lucena, H. Early postoperative voiding dysfunction after insertion of retropubic midurethral tape. <i>Int Urogynecol J</i> 2016; Epub Ahead of Print
Lukacz ES, et al. [Pop 54, 1 yr fu] The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. <i>Int Urogynecol J Pelvic Floor Dysfunct.</i> 2003 Aug;14(3):179-84.
Lukacz, Nager. [Pop 54, 1 yr fu] The effects of the TVT on proximal urethral position: a prospective, longitudinal evaluation. <i>Int Urogynecol J</i> (2003) 14:179-184
Luo, D. Different sling procedures for stress urinary incontinence: a lesson from 453 patients. <i>Kaohsiung Journal of Medical Sciences</i> 2014; 30: 139-145
Lv, J. Risk factors of long-term complications after Tension-Free Vaginal Tape (TVT) procedure in Chinese patients with stress urinary incontinence. <i>Biomedical Research</i> 2015; 26(1): 55-58
Madhuvrata, P. Systematic review and meta-analysis of “inside-out” versus “outside-in” transobturator tapes in management of stress urinary incontinence in women. University of York 2012
Magee, G. A Real-World Comparative Assessment of Complications Following Various Mid-Urethral Sling Procedures for the treatment of stress urinary incontinence. <i>Journal of Long-Term Effects of Medical Implants</i> 2012; 22(4): 329-340
Malek, J. The Effect of Age on Stress and Urgency Urinary Incontinence Outcomes in Women Undergoing Primary Midurethral Sling. <i>Int Urogynecol J</i> 2015; 26(6): 831-835
Mamy L, et al. Correlation between shrinkage and infection of implanted synthetic meshes using animal model of mesh infection. <i>Int Urogynecol J</i> (2011) 22:47-52.
Marsh FA and Assassa P, An Audit of the Introduction of TVT Secur in Clinical Practice. <i>Int Urogynecol J</i> 2007;18(Suppl 1):S25-S105.
Martan. Initial experience with TVT-Secur system procedure and the reason for persistent stress urinary incontinence <i>Int Urogynecol J</i> (2007) 18 (Suppl 1):S25-S105
Mary C, et al. Comparison of the in vivo behavior of polyvinyliden flouride and polypropylene sutures used in vascular surgery. <i>ASAIO Journal</i> 1998; 44:199-206.

## Medical Literature

Masata, J. Comparison of the efficacy of tension-free vaginal tape obturator (TVT-O) and single-incision tension-free vaginal tape (Ajust™) in the treatment of female stress urinary incontinence: a 1-year follow-up randomized trial. <i>Int Urogynecol J</i> 2016; Epub Ahead of Print
Masata, J. Randomized Prospective Trial of a Comparison of the Efficacy of TVT-O and TVT Secur system in the treatment of stress urinary incontinent women - Long-term results with a minimum of five years follow-up. <i>Int Urogynecol J</i> 2015; 26 (Suppl 1): S137-138
Masata, J. Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT Secur systems in the treatment of stress urinary incontinence women - 2-year follow-up. <i>Int Urogynecol J</i> 2012; 23: 1403-1412
Maslow, K. Randomized clinical trial comparing TVT Secur system and trans vaginal obturator tape for the surgical management of stress urinary incontinence. <i>Int Urogynecol J</i> 2014; Epub Ahead of print
Mathias, S. Chronic Pelvic Pain: Prevalence, Health-Related Quality of Life, and Economic Correlates. <i>Obstet Gynecol</i> 1996; 87(3): 321-327
Mazzilli R. Sexual Dysfunction in diabetic women: prevalence and differences in type 1 and type 2 diabetes mellitus. <i>Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy</i> 2015; 8: 97-101
McCracken. Five Year Follow-Up Comparing TVT and Colposuspension; <i>Ulster Med J</i> ; 76 (3) 146-149
McGregor. Evaluation of the carcinogenic risks to humans associated with surgical implants and other foreign bodies - a report of an IARC Monographs Programme Meeting. <i>European Journal of Cancer</i> 36 (2000) 307-313
McGuire, E. Pubovaginal Sling Procedure for Stress Incontinence. <i>J Urol</i> 1978; 119: 82-84
McGuire. Experience with pubovaginal slings for urinary incontinence at the University of Michigan. <i>J. Urol</i> , 138:525-526;1987
Meana, M. Painful Intercourse Genito-Pelvic Pain/Penetration Disorder Chapter 11 in Katherine Hertlein's <i>Systemic Sex Therapy Second Edition</i> . ISBN: 978-0-415-73821-7
Meana, M. Psychosocial Correlates of Pain Attributions in Women With Dyspareunia. <i>Psychosomatics</i> 1999; 40: 497-502
Mellano, E. The Role of Chronic Mesh Infection in Delayed-Onset Vaginal Mesh Complications or Recurrent Urinary Tract Infections: Results from Explanted Mesh Cultures. <i>Female Pelvic Med Reconstr Surg</i> 2016; 00: 00-00
Meschia M, et al. [IUGA Abs 003] A Multicenter Randomized Comparison of Tension-Free Vaginal Tape (TVT) and Trans-Obturator In-Out Technique (TVT-O) For The Treatment of stress urinary incontinence: One year results. <i>Int Urogynecol J</i> (2007) 18 (Suppl 1): S2.
Meschia M, et al., TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence. One year data from a multi-centre prospective trial. <i>Int Urogynecol J Pelvic Floor Dysfunct</i> 2009 Mar;20(3):313-7.
Meschia. [Pop 190, 2 yr fu] TVT and intravaginal slingplasty (IVS) for SUI. A multicenter randomized trial; <i>American Journal of Obstetrics and Gynecology</i> (2006) 195, 1338-42
Miller JM, et al. Clinical Evaluation of Monofilament Polypropylene Suture. <i>Am. Surgeon</i> 33- 666-70. (1967)
Minassian, V. Urinary incontinence as a worldwide problem. <i>International Journal of Gynecology and Obstetrics</i> 2003; 82: 327-338
Minassian. [pop 108] TVT: do patients who fail to follow-up have the same results as those who do?; <i>Neurourology and Urodynamics</i> 24:35-38 (2005)
Misrai, V. Surgical Resection for Suburethral Sling Complications After treatment for Stress Urinary Incontinence. <i>Journal of Urology</i> 2009; 181: 2198-2203

## Medical Literature

Mistrangelo E. Rising use of synthetic mesh in transvaginal pelvic reconstructive surgery: A review of the risk of vaginal erosion. <i>Journal of Minimally Invasive Gynecology</i> . 2007. 14:5. 564-569.
Moalli PA, et al. Tensile Properties of five commonly used mid-urethral slings relative to the TVT. <i>Int Urogynecol J</i> (2008) 19:655-663.
Moalli, Nager. Polypropylene mesh evidence for lack of carcinogenicity. <i>Int Urogynecol J</i> (2014) 25:573-576
Moen, M. A Comparison of Midurethral Sling Versus Burch Urethropexy for Treating Urodynamic Stress Incontinence at the Time of Abdominal Sacrocolpopexy. <i>Journal of Pelvic Medicine &amp; Surgery</i> 2009; 15(2): 56
Mohamad Al-Ali, B. Clinical Impact of Body Mass Index on the Outcome of the SPARC-sling system for the treatment of female stress urinary incontinence. <i>World J Urol</i> 2013; 31: 875-880
Moir J. The Gauze-Hammock Operation. A Modified Aldrige Sling Procedure. <i>The Journal of Obstetrics and Gynaecology of the British Commonwealth</i> Vol. 75, No. 1 January 1968
Molden, S. New Minimally Invasive Slings: TVT Secur. <i>Current Urology Reports</i> 2008; 9: 358-361
Monk. Adhesions after extensive gynecologic surgery: clinical significance, etiology, and prevention. <i>Am J Obstet Gynecol</i> . 1994 May;170(5 Pt 1):1396-403
Moore, R. Minimally Invasive Treatment for Female Stress Urinary Incontinence: (SUI): A Review Including TVT, TOT, and Mini-Sling. <i>Surg Technol In</i> 2009; 18: 157-73
Morgan, J. A Sling operation, using Marlex polypropylene mesh, for treatment of recurrent stress incontinence. <i>Am J Obstet Gynec</i> 1970; 106(3): 369-377
Morgan, J. The Marlex sling operation for the treatment of recurrent stress urinary incontinence: a 16-year review. <i>Am J Obstet Gynecol</i> 1985; 151: 224-6
Mostafa, A. Single-incision mini-slings versus standard Midurethral Slings in Surgical Management of Female stress Urinary incontinence: An updated systematic review and meta-analysis of effectiveness and complications. <i>European Urology</i> 2014; 65: 402-427
Mueller, E. Comparison of flowrates and voided volumes during non-instrumented uroflowmetry and pressure-flow studies in women with stress incontinence. <i>Neurourol Urodyn</i> . 2015; 34(6): 549-553
Mueller, E. Relative efficacy of retropubic and transobturator slings. <i>Nat Rev Urol</i> 2009; 6(10): 523-4
Mueller, E. Retropubic Bladder Neck Suspensions. Chapter 10 in Howard B. Goldman's <i>Complications of Female Incontinence and Pelvic Reconstructive Surgery</i> ISBN 978-1-61779-923-5
Muhl T, et al. New Objective Measurement to Characterize the Porosity of Textile Implants. <i>Wiley InterScience</i> (2007)
Muzsnai, D. Retropubic Vaginopexy for Correction of Urinary Stress Incontinence. <i>Obstetrics &amp; Gynecology</i> 1982; 59:113-118
Myers, E. Differences in recurrent prolapse at 1 year after total vs. supracervical hysterectomy and robotic sacrocolpopexy. <i>Int Urogynecol J</i> 2015; 26: 585-589
Nager (2014) AUGS - Final Presidential Blog
Nager C. Midurethral Slings: Evidence-based Medicine vs. The Medicolegal System. <i>Accepted Manuscript to appear in: American Journal of Obstetrics and Gynecology</i> ; 2016 doi: 10.1016/j.ajog.2016.04.018
Nager CW. Midurethral Slings: Evidence-Based Medicine vs. The Medicolegal System. <i>Am J Obstet Gynecol</i> (2016); 10.1016/j.ajog.2016.04.018.
Nager, C. Synthetic full-length midurethral slings remain the standard of care for SUI surgery. <i>OBG Management</i> 2012; 24(11): 6-7
Nager. [FMPRS] Editorial. AUGS-SUFU Position statement on mesh midurethral slings for SUI. <i>Female Pelvic Medicine &amp; Reconstructive Surgery</i> , Vol. 20, No. 3 (2014)

# Medical Literature

Nager. A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery. N Engl J Med 366; 21 (2012)
Najjai, L. [ICS ABS 401] Comparing Different Types of Suburethral Slings using Perineal Ultrasound. 2012
Najjari, L. Visualization of Polypropylene and Polyvinylidene Fluoride Slings in Perineal Ultrasound and Correlation with Clinical Outcome. BioMed Research International 2014; 181035, 8 pages
Nambiar, A. Single-incision sling operations for urinary incontinence in women (Review). Reprint of 2014 Issue 6; 1-30; Page 20 of Bruce Rosenzweig's 1.15.16 expert report citing Nambiar article.
Nappi, R. Clinical Biologic Pathophysiologies of Women's Sexual Dysfunction. J Sex Med 2005; 2: 4-25
Neuman M, Perioperative complications and early follow-up with 100 TVT-SECUR procedures. J Minim Invasive Gynecol 2008 Jul-Agu;15(4): 480-4.
Neuman M, Training TVT Secur: The First 150 Teaching Operations. Int Urogynecol J 2007;18(Suppl 1):S25-S105.
Neuman M. Transobturator vs. Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-Year Follow-up. Journal of Minimally Invasive Gynecology (2011) 18, 769-773
Neuman M. TVT and TVT-Obturator: Comparison of Two Operative Procedures. Eur J Obstet Gynecol Reprod Biol 131 (2007) 89-92.
Neuman, M. Transobturator vs. Single-Incision Suburethral Mini-slings for treatment of female stress urinary incontinence: early postoperative pain and 3-year follow-up. Journal of Minimally Invasive Gynecology 2011; 18: 769-773; Page 16 of Bruce Rosenzweig's 1.15.16 expert report citing Neuman article.
Neuman, M. TVT and TVT-Obturator: Comparison of two operative procedures. Eur J Obstet Gynecol Reprod Biol 2007; 131: 89-92
Neuman, M. TVT-SECUR: 100 teaching operations with a novel anti-incontinence procedure. Pelviperineology 2007; 26: 121-123
Nguyen J. [Pop 4,142] Perioperative Complications and Reoperations After Incontinence and Prolapse Surgeries Using Prosthetic Implants. Obstet Gynecol. 2012 Mar;119(3):539-46
Nichols DH. The Mersilene Mesh Guaze-Hammock for Severe Urinary Stress Incontinence. Obstet Gynecol 1973; 41(1): 88-93.
Niemczyk, P. United States Experience with Tension-free Vaginal Tape Procedure for Urinary Stress Incontinence: Assessment of Safety and Tolerability. Techniques in Urology 2001; 7(4): 261-265
Nilsson C. [7 yr fu] Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol (2004) 104, 1259-1262
Nilsson C. Creating a gold standard surgical procedure: the development and implementation of TVT. Int Urogynecol J 2015; 26(4): 467-469
Nilsson C. Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence. Int Urogynecol J 2001; (Suppl 2): S5-S8
Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. [Pop 58, 17 yrs fu] Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J (2013) 24: 1265-1269
Nilsson CG. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J (2008) 19: 1043-1047

## Medical Literature

Nilsson M, et al. (Swedish Registry) [Pop 3334, 12 mo fu] Female urinary incontinence: patient-reported outcomes 1 year after midurethral sling operations. <i>Int Urogynecol J</i> . 2012 Oct;23(10):1353-1359.
Nilsson, C. Creating a gold standard surgical procedure: the development and implementation of TVT. <i>Int Urogynecol J</i> 2015; Epub Ahead of Print
Norris, J. Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach. <i>Journal of Endourology</i> 1996; 10(3): 227-230
Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, Artibani W. [meta-analysis] Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. <i>Eur Urol</i> 53 (2008):288-309
Novara. [meta-analysis] Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence; <i>Eur Urol</i> 58 (2010) 218-238
Novara. [review-meta-analysis] Tension-free midurethral slings in the treatment of female stress urinary Incontinence: A Systematic Review and meta-analysis of Randomized Controlled Trials of Effectiveness; <i>Eur Urol</i> 52(2007) 663-679
Nwabineli. [Pop 124, 5 yr fu] Long-term results of urinary stress incontinence treated with mid-urethral tape as a standalone operation or in combination with pelvic floor reconstruction; <i>Journal of Obstetrics and Gynecology</i> , November 2012; 32:773-777
Ogah. Minimally invasive synthetic suburethral sling operations for Stress Urinary Incontinence in Women: a Short version Cochrane Review; <i>Neurourology and Urodynamics</i> 30:284-291 (2011)
Ogah. Minimally invasive synthetic suburethral sling operations. Cochrane Review [Abstract] Cochrane Database Review; The Cochrane Library 2009, Issue 4
Okulu. [Pop144, 4 yr fu,] Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications. <i>Scand J Urol</i> 2013; 47(3): 217-224
Oliphant, S. Trends in Stress Urinary Incontinence Inpatient Procedures in the United States, 1979-2004. <i>Am J Obstet Gynecol</i> 2009; 200(5): 521.e1-521.e6
Oliveira R, et al., Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence. <i>BJU Int</i> 2009 Jul;104(2):225-8.
Olivera, C. Non-Antimuscarinic Treatment for Over Active Bladder: A Systematic Review. (Author's Manuscript) <i>American Journal of Obstetrics and Gynecology</i> 2015 10.1016/j.ajog.2016.01.156
Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. <i>Int Urogynecol J</i> (2010) 21:679-683
Olsson. A Three-Year Postoperative Evaluation of TVT; <i>Gynecol Obstet Invest</i> 1999; 48:257-269
Ong, Thames, White. [IUGA Abs PP 19] The Myth: In Vivo Degradation of Polypropylene Meshes. <i>Int Urogynecol J</i> (2016) 27 (Suppl 1): S37-S38.
Ortega-Castillo, V. Surgical Complications with Synthetic Materials. <i>Urinary Incontinence Edited by Mr. Ammar Alhasso</i> ; 2012 ISBN 978-953-51-0484-1: 241-262
Osborn, D. Obesity and Female Stress Urinary Incontinence. <i>Urology</i> 2013 <a href="http://dx.doi.org/10.1016/j.urology.2013.06.020">http://dx.doi.org/10.1016/j.urology.2013.06.020</a>
Osborn. [Pop 77] Analysis of patient and technical factors associated with MUS mesh exposure and perforation. <i>Int Journal of Urology</i> (2014) 21, 1167-1170

## Medical Literature

Oswald. The deterioration of polypropylene by oxidative degradation. <i>Polymer Engineering and Science</i> , July 1965
Padmanabhan, P. Change in urinary storage symptoms following treatment for female stress urinary incontinence. <i>Int Urogynecol J</i> 2016 Jan 21 Epub ahead of print
Palma F, et al. Vaginal atrophy of women in postmenopause. Results from a multicentric observational study: The AGATA study. <i>Maturitas</i> 83 (2016) 40-44
Pandit A. Design of surgical meshes - an engineering perspective. <i>Technology and Health Care</i> 2004; 12: 51-65
Pandit, L. Postmenopausal Vaginal Atrophy and Atrophic Vaginitis. <i>Am J Med Sci</i> 1997; 314(4): 228-231
Pardo, J. Effectiveness of TVT-Secur compared with miniarc for stress urinary incontinence: a randomized controlled trial with min-sling. <i>Int Urogynecol J</i> 2010; 21(Suppl 1): S322-323
Parnell B, et al. Genitofemoral and Perineal Neuralgia After Transobturator Midurethral Sling. <i>Obstet Gynecol</i> 2012; 119:428-31.
Parnell, J. Management of Recurrent Urinary Stress Incontinence by the Marshall- Marchetti-Krantz Vesicourethropexy. <i>J Urol</i> 1984; 132: 912-914
Pastore AL, et al. [Pop 42, 1 yr fu] Evaluation of sexual function and quality of life in women treated for stress urinary incontinence: tension-free transobturator suburethral tape versus single-incision sling. <i>Journal of Women's Health</i> (2016) 25(4): 1-5
Patel, M. Is Burch or mid-urethral sling better with abdominal sacral colpopexy? <i>Int Urogynecol J</i> 2009; 20: 787-790
Pauls, R. Practice patterns of physician members of The American Urogynecologic Society regarding female sexual dysfunction: results of a national survey. <i>Int Urogynecol J</i> 2005; 16: 460-467
Pearce, M. The Female urinary microbiome in urgency urinary incontinence. <i>Am J Obstet Gynecol</i> 2015; 213: 347.e1-11
Pereira, I. Incontinence surgery in obese women: comparative analysis of short- and long-term outcomes with a transobturator sling. <i>Int Urogynecol J</i> 2016; 27: 247-253
Perkins. The Role of Mid-urethral Slings in 2014_ Analysis of the Impact of Litigation on Practice; <i>Curr Bladder Dysfuct Rep</i> (2015) 10:39-45
Petri, E. Reasons for the treatment of surgical complications with alloplastic slings. <i>Int Urogynecol J</i> 2005; 17: 3-13
Petri. [Pop 359] Complications of synthetic slings used in female SUI and applicability of the new IUGA-ICS classification. <i>Eur J Obstet Gynecol Reprod Biol</i> 165 (2012) 347-351
Petri. Comparison of late complications of retropubic and transobturator slings in stress urinary incontinence. <i>Int Urogynecol J</i> (2012) 23:321-325
Petros & Ulmsten. An integral theory of female urinary incontinence. Experimental and clinical considerations <i>Acta Obstet Gynecol Scand Suppl.</i> 1990;153:7-31.
Petros, P. An Integral Theory and its method for the diagnosis and management of Female Urinary Incontinence. <i>Scandinavian Journal of Urology and Nephrology Supplement No.</i> 153
Petros, P. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond: Ulf Ulmsten Memorial Lecture 2014. <i>Int Urogynecol J</i> 2015. DOI 10.1007/s00192-015-2639-3
Petrou, S. Suprameatal transvaginal urethrolisis. <i>J Urol</i> 1999; 161: 1268-1271
Polat, M. Comparison of the Effect of Laparoscopic and Abdominal Hysterectomy on Lower Urinary Tract Function, Vaginal Length, and Dyspareunia: A Randomized Clinical Trial. <i>Journal of Laparoendoscopic &amp; Advanced Surgical Techniques</i> 2016; 26(2): 116-121

## Medical Literature

Pourdeyehimi B. Porosity of surgical mesh fabrics: new technology. J Biomed. Mater. Res.: Applied Biomaterials, Vol 23, No A1, 145-152 (1989)
Pradhan, A. Surgical management of stress urinary incontinence. Obstetrics, Gynaecology and Reproductive Medicine 2010; 20(7): 207-211
Prakash P, et al. A prospective randomised controlled trial comparing chronic groin pain and quality of life in lightweight versus heavyweight polypropylene mesh in laparoscopic inguinal hernia repair. Journal of Minimal Access Surgery, 2016; 12(2):154-161.
Prien-Larien. [Pop 660, 1 yr fu] Influence of TVT properties on outcomes of midurethral sling. Int Urogynecol J doi 10.1007/s00192-015-2921-4
Prien-Larsen JC, Hemmingsen L. [Pop 316, 5 yr fu] Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. Int Urogynecol J Pelvic Floor Dysfunct (2009) 20:703-709
Quemener, J. Rate of re-interventions after transvaginal pelvic organ prolapse repair using partially absorbable mesh: 20 months median follow-up outcomes. Eur J Obstet Gynecol Reprod Biol 2014; 175: 194-198
Rackley, R. Tension-free Vaginal Tape and Percutaneous Vaginal Tape Sling Procedures. Techniques in Urology 2011; 7(2): 90-100
Raders J, Lucente V, Haff R. [ICS, IUGA Abs 688] Transobturator TVT (TVT-O) "Inside-to-Out" Suburethral Sling for the treatment of Stress Urinary Incontinence: Early U.S. Experience. (2004)
Raders JL, Lucente VR, Murphy M. [Abs. 310] Transobturator TVT (TVT-O) "Inside-Out" Suburethral sling for the treatment of stress urinary incontinence: Early Clinical Experience. (2005)
Rahn, D. Vaginal estrogen use in postmenopausal women with pelvic floor disorders: systematic review and practice guidelines. In Urogynecol J 2014; Epub Ahead of Print
Rapp, D. The Evolution of Midurethral Slings. Nature Clinical Practice Urology 2008; 5(4): 194-201
Rardin, C. Long-term Followup of a Transvaginal Burch Urethropexy for Stress Urinary Incontinence. Journal of Pelvic Medicine & Surgery 2007; 13(2): 73
Rardin, Rosenblatt. Outcomes of TVT in Women With Intrinsic Sphincter Deficiency With or Without Urethral Hypermobility; Journal of Pelvic Medicine & Surgery (2005); 11(6)
Rehman (Bezerra) [Cochrane Review] Traditional suburethral sling operations for urinary incontinence in women (Review); The Cochrane Library 2011, Issue 1
Reich A, Kohorst F, Kreienberg R, Flock F. [7 yr fu] Long-term results of the tension-free vaginal tape procedure in an unselected group: a 7-year follow-up study. Urology (2011) 78:774-777
Reisenauer, C. Transobturator vaginal tape inside-out A Minimally invasive treatment of stress urinary incontinence: Surgical procedure and anatomical conditions. Eur J Obstet Gynecol Reprod Biol 2006; 127: 123-129
Rezapour M. A 3-month preclinical trial to assess the performance of a new TVT-like mesh (TVT <sub>x</sub> ) in a sheep model. Int Urogynecol 2007; 18: 183-187
Rezapour, M. Tension-free vaginal tape (TVT) in stress incontinence women with intrinsic sphincter deficiency (ISD) - A long-term follow-up. Int Urogynecol J 2001 (Suppl 2); S12-14
Rezapour, M. Tension-Free Vaginal Tape (TVT) in Women with Mixed Urinary Incontinence - A Long-Term Follow-up. Int Urogynecol J 2001; (Suppl 2): S15-S18
Rezapour. [Pop 34, 4 yr fu] TVT in Women with Recurrent SUI - A Long-term Follow up; Int Urogynecol J (2001) (Suppl 2) S9-S11
Riachi, Miklos. [case report] Repeat TVT Sling for the Treatment of Recurrent SUI; Int Urogynecol J (2002) 13:133-135
Richter HE, Kenton KS. Retropubic versus Transobturator Midurethral Slings for Stress Incontinence. 10.1056/NEJMoao912658

## Medical Literature

Richter, Brubaker, Zimmern, Sirls (UITN) SISTER [Pop 482, 7 yr fu] Patient Related Factors Associates with Long-Term Urinary Continence After Burch Colposuspension and Pubovaginal Fascial Sling Surgeries. J Urol 2012; 188: 485-489
Richter, H. Demographic and Clinical Predictors of Treatment Failure One Year After Midurethral Sling Surgery. Obstet Gynecol 2011; 117(4): 913-921
Ridgeway, Chen, Paraiso [Clin Ob Gyn] The Use of Synthetic Mesh in Pelvic Reconstructive Surgery. Clin Ob Gyn (2008); 51(1): 136-152
Rinne, K. A randomized trial comparing TVT with TVT-O: 12-month results. Int Urogynecol J 2008; 19: 1049-1054
Robinson, D. What is the best surgical intervention for stress urinary incontinence in the very young and very old? An International Consultation on Incontinence Research Society update. Int Urogynecol J 2015; 26: 1599-1604
Rogers, R. [ICS, IUGA ABS 155] Anatomic Considerations for the TVT-Obturator Approach for the Correction of Female Stress Urinary Incontinence. 2004
Rogo-Gupta L, Raz S. Pain Complications of Mesh Surgery. Current Clinical Urology, DOI 10.10007/978-1-61779-924-2_9
Rogo-Gupta, L. Symptom Improvement After Prolapse and Incontinence Graft Removal in a Case Series of 306 Patients. Female Pelvic Med Reonstr Surg 2015; 21: 319-324
Rogo-Gupta, L. Trends in the Surgical Management of Stress Urinary Incontinence Among Female Medicare Beneficiaries, 2002-2007. Urology 2013; 82(1): 38-41
Roovers J-P. Collaboration with the mesh industry: who needs who? Int Urogynecol J (2016) 27: 1293-1295.
Ross S, et al. Single incision device (TVT Secur) versus retropubic tension-free vaginal tape device (TVT) for the management of stress urinary incontinence in women: a randomized clinical trial. BMC Res Notes. 2014 Dec 22;7:941.
Ross, S. Single incision device (TVT Secur) versus retropubic tension-free vaginal tape device (TVT) for the management of stress urinary incontinence in women: a randomized clinical trial. BMC Research Notes 2014; 7: 1-10
Ross, S. The short life cycle of a surgical device - Literature analysis using McKinlay's 7-stage model. Health Policy and Technology 2015; 4: 168-188
Rostaminia, G. Surgeon preference for surgical treatment of stress urinary incontinence among urogynecologic surgeons, comparison after 15 years. Pelviperineology 2015; 34: 75-78
Roth CC, et al. Synthetic slings: which material, which approach. Curr Opin Urol 2006; 16:234-239.
Roth, T. Management of persistent groin pain after transobturator slings. Int Urogynecol J 2007; 18: 1371-1373
Roy. Cardiovascular sutures as assessed by scanning electron microscopy. Scanning Electron Microscopy 1980 volume III
Rubin EB, et al. States Worse Than Death Among Hospitalized Patients with Serious Illnesses. JAMA Intern Med 2016 AUG 1, DOI: 10.1001.
Ryder. Chronic Pelvic Pain. Am Fam Physician 54 (7), 2225-2237. 1996
Saltz SM, et al., Short-term assessment of patients undergoing the new tension free vaginal tape: Secur procedure for treatment of stress urinary incontinence. Int Urogynecol J 2007;18(Suppl 1):S25-S105.
Schauer. 10 years follow-up after mid-urethral sling implantation: high rate of cure yet a re-occurrence of OAB-Symptoms; Neurourology and Urodynamics DOI 10.1002/nau 2016
Scheiner, D. Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings. Int Urogynecol J 2012; 23: 197-206

# Medical Literature

Schimpf MO, et al. Sling Surgery for stress urinary incontinence in women: a systematic review and metaanalysis. AM J Obstet Gynecol (2014) 211:71.e1-27.
Schimpf MO, Rahn DD, Wheeler TL et al. (published) [meta-analysis] Sling surgery for stress urinary incontinence in women: a systematic review and meta-analysis. Am J Obstet Gynecol (2014) 211:71.e1-71.e27
Schiotz H. [Pop 33,10 yr fu] Ten-year follow-up after conservative treatment of stress urinary incontinence. Int Urogynecol J (2008) 19:911-915
Schoen. 11.1.5 Tissue Response to Injury. Inflammation, Repair and Regeneration (Granulation tissue p464). Biomaterials Science, An introduction to Materials in Medicine, 3 <sup>rd</sup> edition, Section II.1 pp.464-466
Schraffordt Koops, S. Prospective analysis of complications of tension-free vaginal tape from The Netherlands Tension-free Vaginal Tape Study. American Journal of Obstetrics and Gynecology 2005; 193: 45-52
Schraffordt Koops. [Pop 634, 2 yr fu] Quality of life before and after TVT, a prospective multicenter cohort study, results from the Netherlands TVT database; BJOG 2006; 113:26-29
Schraffordt Koops. The effectiveness of tension-free vaginal tape (TVT) and quality of life measured in women with previous urogynecologic surgery; Analysis from the Netherlands TVT database; American Journal of Obstetrics and Gynecology (2006) 195, 439-44
Scientific Committee on Emerging and Newly Identified Health Risks - Opinion on The Safety of Surgical Meshes used in urogynecological Surgery. Approved December 3, 2015
Seklehner, S. A Meta-Analysis of the Performance of Retropubic Mid Urethral Slings Versus Transobturator Mid Urethral Slings. Journal of Urology 2015; 193: 909-915
Seo, J. Comparison between transobturator vaginal tape inside out and single incision sling system in the treatment of female stress urinary incontinence: prospective randomized study. ABS 23; 2011.
Serati M, et al. Is there a learning curve for the TVT-O procedure. A prospective single-surgeon study of 372 consecutive cases. Eur J Obstet Gynecol Reprod Biol 186 (2015) 85-90.
Serati M, Ghezzi F, Cattoni E, Braga A, Siesto G, Torella M, Cromi A, Vitobello D, Salvatore S. [Pop 58, but 10 yrs fu] Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. Eur Urol (2012) 61:939-946
Serati, et al. [Pop 191 5 yr fu] TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. European Urology 63 (2013) 872-878
Serati, M. TVT-O for the Treatment of Pure Urodynamic Stress Incontinence: Efficacy, Adverse Effects, and Prognostic Factors at 5-Year Follow-up. Eur Urol 2013; 63: 872-878
Shaare-Zedek. Training TVT Secur: The first 150 teaching operations Int Urogynecol J (2007) 18 (Suppl 1):S25-S105
Shah. Mesh complications in female pelvic floor reconstructive surgery and their management: A Systemic review. Indian J Urol. 2012 Apr-Jun; 28(2): 129-153
Shah. Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia. Int Urogynecol J (2013) 24:2111-2117
Shao U, et al. [Pop 24, median 57 mo fu] Tension-free vaginal tape retropubic sling for recurrent stress urinary incontinence after Burch colposuspension failure. Int J Urol (2011) 18, 452-457

## Medical Literature

Sheiner, D. FV-Gyn 02.02 Tension-free vaginal Tape TVT Compared with Outside-in TOT and inside-out TVT-O transobturator tapes: a randomized controlled trial. Arch Gynecol Obstet 2010; 282(Suppl 1): S26-27
Shin, Y. Efficacy and safety of the TVT-SECUR® and Impact on Quality of Life in Women with stress Urinary Incontinence: a 2-year follow-up. Korean J Urol 2011; 52: 335-339
Shull BL. Reasonable people disagree: lessons learned from the sling and mesh story. Int Urogynecol J (2016) 27:1289-1291.
Siedhoff, M. Post-hysterectomy Dyspareunia. Journal of Minimally Invasive Gynecology 2014; 21: 567-575
Signorello, L. Postpartum sexual functioning and its relationship to perineal trauma: A retrospective cohort study of primiparous women. Am J Obstet Gynecol 2001; 184: 881-90
Silverstein. Smoking and wound healing. Am J Med . 1992 Jul 15;93(1A):22S-24S.
Sindhwani, N. Immediate postoperative changes in synthetic meshes - In vivo measurements. Journal of the Mechanical Behavior of Biomedical Materials 2015; 55: 228-235
Sobhgol, S. Rate and related factors of dyspareunia in reproductive age women: a cross-sectional study. International Journal of Impotence Research 2007; 19: 88-94
Soergel TM, Shott S, Heit M. Poor surgical outcomes after fascia lata allograft slings. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12(4):247-53.
Sola, V. Third Generation Sub-Mid Urethral Mesh: Experience with 110 TVT-Secur. Arch.Esp.Urol. 2009; 62(5): 376-388
Sola, V. TVT versus TVT-O for minimally invasive surgical correction of stress urinary incontinence. International Braz J Urol 2007; 33(2): 246-253
Sommer, T. Dynamesh® in the repair of laparoscopic ventral hernia: a prospective trial. Hernia 2013; 17(5): 613-8
Song PH, Kim YD, Kim HT, Lim HS, Hyun CH, Seo JH, Yoo ES, Park CH, Jung HC, Gomelsky A. [Pop 306, 7 yr fu] The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. BJU Int. 2009 Oct;104(8):1113-1117.
Song, et al. The long-term outcomes of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence: data for minimum 13 years of follow-up. LUTS (2017) 9, 10-14.
Song, X. The value of the preoperative 1-h pad test with pessary insertion for predicting the need for a mid-urethral sling following pelvic prolapse surgery: a cohort study. World J Urol 2015; Epub Ahead of Print
Song. [EAU Poster 771] Ten-Year Outcomes of the TVT Procedure for Treatment of Female SUI; Eur Urol Suppl 2011; 10(2):244
Song. [Pop 206, 13 yr fu] AUA Abs. MP33-03 The long-term outcomes from TVT procedure for female SUI; Data from minimal 13 years of follow up; <a href="http://www.aa2014.org">http://www.aa2014.org</a> 2014
Spitznagle, T. Myofascial Pelvic Pain. Obstet Gynecol Clin N Am 2014; 41: 409-432
Stanford, Paraiso. A Comprehensive Review of Suburethral Sling Procedure Complications. Journal of Minimally Invasive Gynecology (2008) 15, 132-145
Stanford. [rabbit] IUGA Abs. 104 Evaluation of Local Tolerance and of Tissue Integration with a Knitted Urethral Support Prosthesis in Rabbits. Int Urogynecol J (2006) 17 (Suppl 2):S101-S152
Stanton, S. Stress Incontinence. Why and How Operations Work. Urol Clin North Am 1985; 12(2): 279-84
Steege, J. Evaluation and Treatment of Dyspareunia. Obstet Gynecol 2009; 113(5): 1124-1136
Sternschuss, Ostergard. (published) Letter to Editor RE: Post implantation alterations of polypropylene in the human. J Urol Vol. 188, 27-32, 2012

## Medical Literature

Strus. The in vitro effect of hydrogen peroxide on vaginal microbial communities. <i>FEMS Immunol Med Microbiol</i> 48 (2006) 56-63
Summit, R. Suburethral sling procedure for genuine stress incontinence and low urethral closure pressure. A Continued Experience. <i>Int Urogynecol J</i> 1992; 3: 18-21
Summitt, R. Urinary incontinence: Correlation of history and brief office evaluation with multichannel urodynamic testing. <i>Am J Obstet Gynecol</i> 1992; 166: 1835-44
Sung, V. Comparison of Retropubic versus Transobturator Approach to Midurethral Slings: A Systematic Review and Meta-Analysis. <i>Am J Obstet Gynecol</i> 2007; 197(1): 3-11
Suskind, A. Effectiveness of Mesh Compared With Nonmesh sling surgery in Medicare Beneficiaries. <i>Obstet Gynecol</i> 2013; 0: 1-7
Svabik K, et al. Ultrasound appearances after mesh implantation-evidence of mesh contraction or folding? <i>Int Urogynecol J</i> (2011) 22:529-533.
Svenningsen R, et al. (Norwegian registry) [Pop 542, median 129 mo fu] Long-term follow-up of the retropubic tension-free vaginal tape procedure. <i>Int Urogynecol J</i> . 2013 Aug;24(8):1271-1278
Svenningsen R. [Pop 810, 10 yr fu] Risk Factors for Long-Term Failure of the Retropubic Tension-Free Vaginal Tape Procedure. <i>Neurourology and Urodynamics</i> (2013) 33:1140-1146, DOI 10.1002/nau.2013
Sweat. Polypropylene mesh tape for SUI- complications of urethral erosion and outlet obstruction. <i>J Urol Vol.</i> 168, 144-146, July 2002
Tammaa. [Pop 302, 5 yr fu] SGS Poster 18 Retropubic versus Transobturator TVT: Five-year results of the Austrian Trial; Abstracts / <i>Journal of Minimally Invasive Gynecology</i> 21 (2014) S1-S24
Tamussino K. (Austrian registry) [Pop 2543] Transobturator tapes for stress urinary incontinence: Results of the Austrian registry. <i>Am J Obstet Gynecol</i> 2007;197:634.e1-634.e5.
Tamussino KF, et al. Tension-free vaginal tape operation: Results of the Austrian Registry. <i>Obstet Gynecol</i> 2001; 98:732-736.
Tan PF, Yang LL, Ou RB, Tang P, Yang WJ, Huang JB, Wei W, Wei XH, Wang B, Xie KJ. Effectiveness and complication rates of tension-free vaginal tape, transobturator tape, and tension-free vaginal tape-obturator in the treatment of female stress urinary incontinence in a medium- to long-term follow up. Meta-analysis of randomized controlled trials. <i>Saudi Med J</i> (2014) 35:20-32
Tang X, et al., Outcome and sexual function after transobturator tape procedure versus tension-free vaginal tape SECUR: a randomized controlled trial. <i>Menopause</i> . 2014 Jun;21(6):641-5.
Tartaglia, E. Third-Generation Tension-free Tape for Female Stress Urinary Incontinence. <i>The Journal of Urology</i> 2009; 182: 612-615
Thames. The myth: in vivo degradation of polypropylene based meshes <i>Int Urogynecol J</i> Published online Sept 2016
Thomas, A. [IC ABS 153] One Year Results of A Prospective Randomized Trial Comparing The Original Inside-Out Transobturator (TVT-O™) Procedure and Modified Version Using a Shortened Tape and Reduced Dissection for the treatment of Female Stress Urinary Incontinence. 2010
Thubert, Deffieux. [Pop 98, 1 yr fu] Bladder injury and success rates following retropubic mid-urethral sling: TVT EXACT™ vs. TVT™ <i>Eur J Obstet Gynecol Reprod Biol</i> 2016; 198: 78-83
Thubert, T. Outcomes associated with the use of midurethral slings for stress incontinence surgery according to the type of hospitalization. <i>Int J Gynecol Obstet</i> 2015; 129: 123-127
Timbrook Brown, E. Evaluation and Management of Mid-Urethral Sling Complications. <i>Curr Bladder Dysfunct Rep</i> 2016; 11: 160-168
Tincello. The TVT Worldwide Observational Registry for Long Term Data: Safety and Efficacy of Suburethral Sling Insertion Approaches for Stress Urinary Incontinence in Women. <i>J Urol</i> (2011); 186: 2310-2315

## Medical Literature

Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. <i>Int Urogynecol J</i> (2015) DOI 10.1007/s00192-015-2645-5
Tommaselli GA, et al. Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study. <i>Eur J Obstet &amp; Gynecol and Reprod Biol</i> 2015;185:151-55
Tommaselli, G. [ICS ABS 357] Vaginal Exposure in Long-Term Follow-up Studies Evaluating Tran-obturator Tapes for the Surgical Treatment of Female Stress Urinary Incontinence: A Systematic Review of the Literature. 2015
Tommaselli, G. [ICS,IUGA ABS 867] Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up. <i>Int Urogynecol J</i> 2010; 21: 1211-1217
Tommaselli, G. Efficacy and safety of the trans-obturator TVT-Abbrevio device in normal weight compared to overweight patients affected by stress urinary incontinence. <i>Eur J Obstet Gynecol Reprod Biol</i> 2016; 197: 116-119
Tommaselli, G. Tension-free vaginal tape-o and -secur for the treatment of stress urinary incontinence: a thirty-six - month follow-up single-blind, double-arm, randomized study. <i>Journal of Minimally Invasive Gynecology</i> 2013; 20: 198-204
Tommaselli, G. TVT-Secur for the treatment of female stress urinary incontinence: a 24-month follow-up retrospective study. <i>Arch Gynecol Obstet</i> 2012; 286: 415-421
Toozs-Hobson. Does age affect the outcome of suburethral tape surgery? The Importance of national registries in answering bigger questions; <i>Int Urogynecol J</i> DOI 10.1007/s00192-016-2995-7
Trabuco, E. Medium-term comparison of continence rates after rectus fascia or midurethral sling placement. <i>Am J Obstet Gynecol</i> 2009; 200:300.e1-300.e6
Trabuco. [Pop 1,375, 10 yr fu] Midurethral Slings for the Treatment of SUI. Long-term Follow-up; <i>Obstetrics and Gynecology</i> Vol. 123, No. 5 (Supplement), May 2014
Trehan & Sanaullah. Laparoscopic posthysterectomy vaginal vault excision for chronic pelvic pain and deep dyspareunia. <i>J Minim Invasive Gynecol.</i> 2009 May-Jun;16(3):326-32
Tucker, P. Prevalence of sexual dysfunction after risk-reducing salpingo-oophorectomy. <i>Gynecol Oncol</i> 2015; <a href="http://dx.doi.org/10.1016/j.gyno.2015.11.002">http://dx.doi.org/10.1016/j.gyno.2015.11.002</a>
Tunn R, et al. Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women w cystocele or rectocele. <i>Ultrasound Obstet Gynecol</i> 2007; 29:449-452.
Tzartzeva, Zimmern, et al. [ICS Abs 366] In-depth nano-investigation of vaginal mesh and tape fiber explants in women. (2014)
Tzartzeva, Zimmern. [Abs M36] Who reports sling and mesh complications to the utilization of the manufacturer and user facility device experience (Maude) database?; <i>Neurourology and Urodynamics</i> DOI 10.1002/nau 2014
Ulmsten U. An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence. <i>Int Urogynecol J</i> 1996; 7:81-86
Ulmsten U. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond. Ulf Ulmsten Memorial Lecture 2014. <i>Int Urogynecol</i> 2015; 26(6): 787-9
Ulmsten U. Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for treatment of Female Urinary Incontinence. <i>Scand J Urol Nephrol</i> 1995; 29:75-82
Ulmsten, Nilsson. [Pop 131, 12 mo fu] Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence. <i>Int Urogynecol J</i> 1998; 9:210-213
Ulmsten, U. An Introduction to tension-free vaginal tape (TVT) - A new surgical procedure for treatment of female urinary incontinence. <i>Int Urogynecol J</i> 2001 (Suppl 2): S3-S4

## Medical Literature

Ulmsten, U. Different Biochemical composition of connective tissue in continent and stress incontinent women. <i>Acta Obstet Gynecol Scand</i> 1987; 66: 455-457
Ulmsten, U. The Basic Understanding and Clinical Results of Tension-free vaginal tape for stress urinary incontinence. <i>Urologe</i> 2001; 40: 269-273
Ulmsten. A three year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. <i>BJOG</i> Vol 106 Issue 4 April 1999 345-350
Ulrich, D. 10-Year Follow-up after the TVT-O Procedure for Stress Urinary Incontinence. <i>Int Urogynecol J</i> 2015; 26(Suppl 1): S146-147
Unger CA, et al. [Pop 267] Indications and risk factors for midurethral sling revision. <i>Int Urogynecol J</i> . 2015; DOI:10.1007/s00192-015-2769-7.
Unger, Ridgeway, Rizzo. [POP 267] Indications and risk factors for midurethral sling revision. <i>Int Urogynecol J</i> (2015); doi: 10.1007/s00192-015-2769-7
Valpas, Nilsson. [Pop 121, 5 yr fu] TVT versus laparoscopic mesh colposuspension: 5-year follow-up results of a randomized clinical trial; <i>Int Urogynecol J</i> , DOI 10.1007/s00192-014-2454-2, 2014
Valpas. Tension-TVT and laparoscopic mesh colposuspension for SUI; <i>Obstetrics and Gynecology</i> , Vol. 104, No. 1, July 2004
Valvekens, E. Long-term outcome of surgical treatment of chronic postoperative groin pain: a word of caution. <i>Hernia</i> 2015; 19: 587-594
Van Geelen, J. The clinical and urodynamic effects of anterior vaginal repair and Burch colposuspension. <i>Am J Obstet Gynecol</i> 1988; 159: 137-44
Van Rensburg, J. OP 107 Single Incision - Needleless and inside-out TVT-O: a multicenter clinical equivalent randomized trial with preliminary 6 months and one year outcome for stress urine continence. <i>Int Urogynecol J</i> 2015; 26 (Suppl1): S136-137
Vassallo. Management of iatrogenic vaginal constriction. <i>Obstet Gynaecol</i> 2003; 101:512-20
Vilhena, V. Female stress urinary incontinence treatment with three different tapes-a seven-year experience. <i>Int Urogynecol J</i> 2011; 22(Suppl 3): S1816
Wai. Patient Satisfaction after midurethral sling surgery for SUI; <i>Obstetrics and Gynecology</i> , Vol. 121, No. 5, May 2013
Walsh, C. TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months. <i>BJU International</i> 2011; 108: 652-657
Walters, M. Which Sling for Which SUI patient? <i>OBG Management</i> 2012; 24(5): 28-40
Waltregny d, de Leval J. The TVT-obturator surgical procedure for the treatment of female stress urinary incontinence: a clinical update. <i>Int Urogynecol J</i> (2009) 20:337-348.
Waltregny D, et al. [EAU Abs. 53] Inside-out transobturator vaginal tape (TVT-O)- One-year results of a prospective study. <i>Eur Urol Suppl</i> 4 (2005) No. 3. Pp. 16
Waltregny D, et al. Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup. <i>Journal of Urology</i> 2006; 175: 2191-2195.
Waltregny D, et al. TVT-O for the treatment of female SUI. Results of a prospective study after a 3-year minimum follow-up. <i>Eur Urol</i> 53 (2008) 401-410.
Waltregny et al. Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: Interim results of a prospective study after a 1 yr minimum follow up. <i>J. Urology</i> . Vol 175, 2191-2195. June 2006
Waltregny et al. TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow Up. <i>European Urology</i> 53 (2008) 401-410.
Waltregny, D. New Surgical Technique for Treatment of Stress Urinary Incontinence TVT-Abbrevio: From Development to Clinical Experience. <i>Surg Technol IN</i> 2012; 22: 149-57

## Medical Literature

Waltregny, D. The TVT-obturator surgical procedure for the treatment of female stress urinary incontinence: a clinical update. <i>Int Urogynecol</i> 2009; 20: 337-348
Wang AC, et al. [Pop 670, approx 2 yr fu] A histologic and immunohistochemical analysis of defective vagina healing after continence taping procedures: A prospective case-controlled pilot study. <i>American Journal of Obstetrics and Gynecology</i> (2004) 191, 1868-74.
Wang, Y. Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. <i>Int Urogynecol J</i> 2011; 22: 1369-1374
Ward, Hilton. [Pop 344, 5 yr fu IRELAND study] Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. <i>BJOG</i> 2008; 115: 226-233
Ward, K. (BMJ) [IRELAND] Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. <i>BMJ</i> 2002; 325: 1-7
Ward, K. A Prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up. <i>American Journal of Obstetrics and Gynecology</i> 2004; 190: 324-31
Ward, K. ABS 50 [Pop 177, 5 yr fu] Multicentre randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: five year follow up. <i>Neurology &amp; Urodynamics</i> 2006
Ward, K. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. <i>BJOG</i> 2008; 115:226-233
Weber, A. Commentary on Brown's 2000 Urinary Incontinence Risk is Increased after Hysterectomy. <i>Evidence-Based Obstetrics and Gynecology</i> 2001; 3: 52-53
Weinberger, M. Postoperative catheterization, urinary retention, and permanent voiding dysfunction after Polytetrafluoroethylene Suburethral Sling Placement. <i>Obstet Gynecol</i> 1996; 87: 50-4
Welk B. (Pop 60K) Removal or Revision of Vaginal Mesh used for the Treatment of Stress Urinary Incontinence. <i>JAMA Surg</i> (2015) Doi:10.1001/jamasurg.2015.2590
Weyhe D, et al. Experimental comparison of monofilament light and heavy polypropylene meshes: less weight does not mean less biological response; <i>World J Surg</i> (2006) 30: 1586-1591
Williams DF. On the mechanisms of biocompatibility. <i>Biomaterials</i> 29 (2008) 2941-2953.
Williams TH, TeLinde RW. The Sling Operation for Urinary Incontinence Using Mersilene Ribbon. <i>Obstet Gynecol</i> 1962; 19(2):241-245.
Williams, D. The Biodegradation of Surgical Polymers. <i>Polyurethanes in Biomedical Engineering</i> , edited by H. Pnack, et al., Amsterdam 1984 - Printed in the Netherlands: 93-102
Williams, E. Stress urinary incontinence: the evolution of the sling. <i>Expert Rev. Med. Devices</i> 2008; 5(4): 507-523
Williams. Review Biodegradation of surgical polymers. <i>Journal of Materials Science</i> 17 (1982) 1233-1246
Wiltz, A. Management of Vaginal Synthetic Graft Extrusion following Surgery for stress Urinary Incontinence and Prolapse. <i>Curr Urol</i> 2009; 3: 82-86
Wiskind, A. The incidence of genital prolapse after the Burhc colposuspension. <i>Am J Obstet Gynecol</i> 1992; 167(2): 399-405
Withagen M, et al. Risk Factors for Exposure, Pain, and Dyspareunia after Tension-Free Vaginal Mesh Procedure. <i>Obstet Gynecol</i> (2011) 118: 629-36.
Wood AJ, et al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. <i>J Mater Sci: Mater Med</i> (2013) 24:1113-1122.

# Medical Literature

Wood LN and Anger JT. [Review] Urinary Incontinence in women. BMJ (2014); 349: g4531, doi: 10.1136/bmj.g4531.
Woodruff AJ, Cole EE, Dmochowski RR, Scarpero HM, Beckman EN, Winters JC. Histologic comparison of pubovaginal sling graft materials: a comparative study. Urology. 2008 Jul;72(1):85-9. doi: 10.1016/j.urology.2008.03.012
Woodruff AJ, et al. Histologic comparison of pubovaginal sling graft materials: A comparative study. Urology 72 (2008) 85-89.
Woods, M. Presentation 452- Durability and feasibility of TVT-Secur placed under local anesthetic in the office setting a 3 year follow up. IUGA ABS NDP01; 2012
Woods, M. Vaginal Sling for Stress Urinary Incontinence Under Local Anesthetic in the Office Setting. Journal of Pelvic Medicine & Surgery 2008; 14(4): 268
Wu, C. The surgical trends and time-frame comparison of primary surgery for stress urinary incontinence, 2006-2010 vs. 1997-2005: a population-based nation-wide follow-up descriptive study. Int Urogynecol J 2014; 25: 1683-1691
Wu, J. Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050. Am J Obstet Gynecol 2011; 205(3): 230.e1-230.e5.
Wu, J. Trends in inpatient urinary incontinence surgery in the USA, 1998-2007. Int Urogynecol J 2011; 22: 1437-1443
Yalcin. [Pop 61, 2 yr fu] Results of TVT operations alone and combined with other vaginal surgical procedures; Arch Gynecol Obstet (2004) 269-96-98
Yonguc, T. Effectiveness of Transobturator Tape Procedure in Obese and Severely Obese Women: 3-Year Follow-Up. Urology 2015; 86: 244-249
York Health Economics Consortium - Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse. Final Report. November 2012
Younes, G. Vaginal adhesions after transvaginal pelvic reconstructive surgeries: prevalence and clinical implications. Int Urogynecol J 2016; 27: 141-145
Young, Rosenblatt, et al. The Mersilene mesh suburethral sling: a clinical and urodynamic evaluation. Am J Obstet Gynecol 1995; 173; 1719-26
Zacharakis. Occult SUI in women with pelvic organ prolapse Is the one step surgical approach a risky choice?; Female Pelvic Medicine & Reconstructive Surgery; Volume 22, Number 1, January/February 2016
Zhang, Z. Retropubic tension-free vaginal tape and inside-out transobturator tape: a long-term randomized trial. Int Urogynecol J 2015; Epub Ahead of Print
Zinn, P. Chronic Pelvic Pain. South African Family Practice 2015; 57(1): 4-9
Zondervan, K. Prevalence and incidence of chronic pelvic pain in primary care: evidence from a national general practice database. British Journal of Obstetrics and Gynaecology 1999; 106: 1149-1155
Zullo MA, et al. One-Year Follow-up of Tension-free Vaginal Tape (TVT) and Trans-obturator Suburethral Tape from Inside to Outside (TVT-O) for Surgical Treatment of Female Stress Urinary Incontinence: A prospective randomized trial. Eur Urol 51 (2007) 1376-1384.
Zyczynski H. [Pop 597 2 yr fu] Sexual activity and function in women more than 2 years after midurethral sling placement. Am J Obstet Gynecol 2012; 207: 421.e1-6
Zyczynski, Goldman, Sirls (UITN) - Change in overactive bladder symptoms after surgery for SUI in women. Obstet Gynecol 2015;126:423-30

**Production Materials**

<b>Document Description [Bates Range]</b>
[000061-63] Version A – TVT Secur Harms/Hazards Table
2003 (14 Day Rabbit Study) PSE 02-0579 Stamped Copy March 10, 2003 R&D - Central File: ETH-11280; ETH-11285-297; ETH-11312-315
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2011 Native Pelvic Organ Prolapse Patient Counseling Guide
2013 Hinoul Clinical Evaluatiown Report - Gynecare TVT™ Family of Products
91 Day Tissue Reaction Study
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
Axel Arnaud, M.D. Powerpoint presentation titled Graft or No Graft
Bacterial Analysis of Explanted Transvaginal Meshes
Biocompatibility of Meshes
Chronology - D-9
DEPO.ETH.MESH.00000367-68 - T-2265 (Prolene Explants - IR Microscopy)
DEPO.ETH.MESH.00004755 - Guidoin Explant
DEPO.ETH.MESH.00004755 - Report: Quebec Explants. 1.20.88
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH MESH 05795421-508 - Gynecare TVT Tension-Free Support for Incontinence: Professional Education Slides.
ETH MESH 08476210-6342 - TVT 510(k)
ETH.MESH.00006636 - Interim report mesh explants pelvic floor repair
ETH.MESH.00006796 - Presentation-Stand and Deliver-Pelvic Floor Repair
ETH.MESH.00030098 - Memo from Anthony Powell and Marianne Kaminski to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy
ETH.MESH.00034061-069 - Gynecare TVT SECUR* System: Key Technical Points
ETH.MESH.00034720-724 - Rezapour, M. A 3-month preclinical trial to assess the performace of a new TVT-like mesh (TVT <sub>x</sub> ) in a sheep model. Inte Urogynecol J 2006
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00074499 - Gynecare Prolift +M-Training Presentation
ETH.MESH.00082668-691 - August 23, 2005 Memo to Dan Smith RE: Final report, PSE Accession Number 05-0396, PROJECT Number 67379
ETH.MESH.00128978-979 - Email from Jacqueline Russo-Jankewicz to Devon Prutzman December 2, 2007 RE: TVT-S Australia standby
ETH.MESH.00130934-41 - July 30, 1998 Meeting Notes re TVT
ETH.MESH.00130950 - ABS 004 An Evaluation of the Gynecare TVT Secur® System (tension-free support for incontinence) for the treatment of stress urinary incontinence.
ETH.MESH.00130950 - Karram, M. ABS 004 An Evaluation of the Gynecare TVT Secur* System (Tension-free support for incontinence) for the treatment of stress urinary incontinence.
ETH.MESH.00134794 - Email from Jason Hernandez to Nicholas Antoun February 27, 2009 RE: TVT WORLD Board meeting presentation; Powerpoint TVT WORLD Registry Maximizing the investment EWHU Board March 2, 2009
ETH.MESH.00143177-185 - Lucente, V. ABS 49 TVT Secur Sugical Technique and Learning Tips and Tricks.
ETH.MESH.00147507-509 - Approved September 16, 2008 - Marketing Services

**Production Materials**

ETH.MESH.00153882-885 - Email from David Robinson to Andrew Meek December 17, 2006 RE: TVT SECUR Conf Call Summary
ETH.MESH.00153967-968 - Email from David Robinson to Dharini Amin November 14, 2006 RE: TVT-S Preceptor Meeting Discussion
ETH.MESH.00158248-253 - Performance Evaluation Test Report: Corporate Product Characterization
ETH.MESH.00161131-32 - TVT-Innovative Surgical Alternative for the Treatment of Female SUI
ETH.MESH.00163952-960 - Gynecare TVT SECUR* System: Key Technical Points
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00211259-60 - Email string re - TVT Exact IFU
ETH.MESH.00214524-529 - Email from Quentin Manley to Barbara Schwartz December 2, 2005 RE: TVT SECUR Minutes – Team Meeting November 22 <sup>nd</sup> 2005_ Agenda November 29 <sup>th</sup> 2005
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00259473-503 - Exhibit T-254
ETH.MESH.00260591-592 - Dan Smith Email Plaintiff's Exhibit 180
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00274015 - One year prospective follow-up of the TVT-S Procedure for treatment of Stress Urinary Incontinence.
ETH.MESH.00295355 - Gynecare TVT Exact Profession Education Slide Deck.
ETH.MESH.00303084-85 - Email string re-Complaint Summaries
ETH.MESH.00308094 - Gynecare TVT SECUR* System Tension-free Support for Incontinence
ETH.MESH.00308557-577 - LPT Report No. 19284/05
ETH.MESH.00309254-350 - Technical File Amendment - Laser Cut Mesh Product Code 830041BL. Septemeber 12, 2006
ETH.MESH.00311792-794 - Email from Aran Maree to Fiona Smith November 12, 2007 RE: FW: Australia update and telephone call with Prof Frazer
ETH.MESH.00311819-820 - Email from David Robinson to Dan Smith March 1, 2007 RE: User Recommendation for TVT Secur
ETH.MESH.00312179-182 - Email from Catherine Beath to Aran Amree November 2, 2007 RE: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.00318306-307 - Email from Mark Yale to Aran Maree February 6, 2008 RE: Discussion Minutes: TVT-Secur follow up with Australia Discuss
ETH.MESH.00318316-317 - Email from Aran Maree to Christiana Bielinski January 10, 2008 RE: FW: TVT Secur Slide Set (Commerical-inconfidence)SEC=UNCLASSIFIED]
ETH.MESH.00318738-748 - Email from Mark Yale to Luis Blanco June 20, 2008 RE: URGENT: Medical Devices Vigilance System – TVT Secur complaint, our file #10100067834 (torn mesh), Filr # 10100068332 (hematoma)
ETH.MESH.00321804-05 - Definition for Major Invasive Surgeries
ETH.MESH.00324086-088 - Email from Carolyn Brennan to Luis Blanco January 22, 2007 RE: Complaints TVT Secur – Germany
ETH.MESH.00326842-846 - Email from Catherine Beath to Sheri McCoy November 5, 2007 RE: URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.00326842-846 - Email from Catherine Beath to Sheri McCoy November 5, 2007 RE: URGENT: Meetiong with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.00327060-063 - Email from David Robinson to Catherine Beath November 12, 2007 RE: Australia update and telephone call with Prof Frazer

**Production Materials**

ETH.MESH.00328977 - Email from Renee Selman to Mark Yale March 20, 2007 RE: Conflict with Town hall
ETH.MESH.00329001-002 - Agenda & Minutes; TVT-Secur PQI07-041 Quality Board November 16, 2007
ETH.MESH.00329316-317 - Email from Mark Yale to David Robinson November 6, 2006 RE: TVT-S Complaint Review
ETH.MESH.00329557-558 - Email from Mark Yale to Sergio Gadaleta March 1, 2007 RE: user recommendation for TVT Secur
ETH.MESH.00330141 - Email from Mark Yale to Konrad Schmitt February 13, 2007 RE: TVT-S
ETH.MESH.00330408 - Email from Mark Yale to Ted Foltyn November 15, 2007 RE: TVT-S in Australia
ETH.MESH.00330962-964 - Email from Christiana Bielinski to Aran Maree February 26, 2008 RE: FW: Communication to Surgeons Regarding the Gynecare TVT Secure System No Protective Marking - SEC=UNCLASSIFIED]
ETH.MESH.00332958 - Email from Patty Lancos to Jackie Sauer August 27, 2008 RE: PQI on TVT-S
ETH.MESH.00333695-696 - Email from Cheryl Bogardus to Dan Smith April 3, 2007 RE: TVT-S
ETH.MESH.00334646-647 - Email from Jonathan Meek to Mark Yale January 9, 2008 RE: TGA Meeting
ETH.MESH.00339437-42 - Gynecare TVT - 5 Years of Proven Performance
ETH.MESH.00349228-37 - Ethicon Memo to C. Linsky Re: Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device 8.8.1997
ETH.MESH.00354732 - Gynecare TVT Abbrevio Professional Education.
ETH.MESH.00365960-965 - Gynecare TVT Secur System Procedural Pearls & Frequently Asked Questions.
ETH.MESH.00369995 - Treatment of Stress Urinary Incontinence with the Gynecare TVT Family of Products.
ETH.MESH.00369999 - Treatment of Stress Urinary Incontinence with GYNECARE TVT SECUR* System
ETH.MESH.00370392 - GYNECARE TVT SECUR* System Early Surgical Experience
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
ETH.MESH.00403003-017 - Cadaver Protocol/ Competition Report
ETH.MESH.00406656 - March 20, 2009 Letter to Oscar Aguirre RE: TVT WORLD Registry
ETH.MESH.00406790 - March 20, 2009 Letter to Radhika Ailawadi RE: TVT WORLD Registry
ETH.MESH.00406854 - March 20, 2009 Letter to Gunhilde Buchsbaum RE: TVT WORLD Registry
ETH.MESH.00407016 - March 20, 2009 Letter to Denise Elser RE: TVT WORLD Registry
ETH.MESH.00407182 - March 20, 2009 Letter to Nicholas Franco RE: TVT WORLD Registry
ETH.MESH.00407285 - March 20, 2009 Letter to Douglas Grier RE: TVT WORLD Registry
ETH.MESH.00407592 - March 20, 2009 Letter to Michael Karram RE: TVT WORLD Registry
ETH.MESH.00407863 - March 20, 2009 Letter to John Nguyen RE: TVT WORLD Registry
ETH.MESH.00407924 - March 20, 2009 Letter to James Raders RE: TVT WORLD Registry
ETH.MESH.00407950 - March 20, 2009 Letter to Douglas VanDrie RE: TVT WORLD Registry
ETH.MESH.00518646-648 - Email from David Robinson to Harel Gadot RE: Clinical Strategy for SECUR June 20, 2006
ETH.MESH.00519476-481 - Email from Dan Smith to Jessica X. Shen December 19, 2006 RE: TVT-S Cookbooks
ETH.MESH.00523617-618 - Summary of Gynecare TVT Secur* System Critical Steps
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh

**Production Materials**

ETH.MESH.00526773-774 - 5/11/06 Ethicon Women's Health & urology Gynecare TVT Secur Press Release Questions & Answers
ETH.MESH.00527118-121 - Email from Joy Hovespian to Dharini Amin August 28, 2007 RE: FW: Dr. Sepulveda's notes summary/PLEASE DO NOT DISTRIBUTE. JUST FOR INTERNAL REVIEW
ETH.MESH.00527624-629 - Email from Dan Smith to David Robinson March 9, 2007 RE: DRAFT of the latest "cookbook" after my trip to Germany
ETH.MESH.00527802 - Email from David Robinson to Dharini Amin April 22, 2007 RE: Secur video
ETH.MESH.00527808-811 - Email from Dharini Amin to Harel Gadot May 17, 2007 RE: TVT SECUR EU Experts meeting – feedback & future actions
ETH.MESH.00527824-827 - Email from Axel Arnaud to Dharini Amin May 21, 2007 RE: TVT SECUR EU Experts Meeting – Feedback & Future Actions
ETH.MESH.00527832-836 - Email from Dan Smith to Harel Gadot May 22, 2007 RE: TVT SECUR EU Experts meeting – feedback & futures actions
ETH.MESH.00528121 - Talking Points for Clinical Plan for Gynecare TVT Secur® System
ETH.MESH.00528140 - Email from David Robinson to Linda Linton September 7, 2006 RE: TVT SECUR convention panel for reps
ETH.MESH.00528157 - Email from David Robinson to Sergio Gadaleta September 7, 2006 RE: Less Dissection
ETH.MESH.00528168-171 - Email from Dan Smith to Axel Arnaud December 18, 2006 RE: TVT-S Cookbooks
ETH.MESH.00528179 - Email from David Robinson to Bob Roda December 29, 2006 No Subject
ETH.MESH.00528184-185 - Minutes TVT Secur resolution team First meeting 1/22/07
ETH.MESH.00528255 - A Multi-Centre, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the TVT-Secur System. 5-week results. D Robinson, MD
ETH.MESH.00529863 - Chart listing type of study, protocol #, protocol nickname, protocol title and investigators.
ETH.MESH.00533250-256 - TVT-World-Wide Observational Registry for Long-Term Data TVT-World Protocol: 300-06-006 Protocol Amendment 2: April 28, 2009 Summary of Changes: 11-21
ETH.MESH.00533283-286 - Communication Plan to Close TVT WORLD Registry
ETH.MESH.00533285-286 - Timelines for communicating information to investigators
ETH.MESH.00539862-869 - TVT-World-Wide Observational Registry for Long-Term Data TVT-World Protocol 300-06-006
ETH.MESH.00541187-190 - Email from Carolyn Brennan to Joseph Scavona September 11, 2009 RE: TVT Secur Inserters Heads Up
ETH.MESH.00541379- Memo to File RE: Mesh Draying for TVT Devices 11.18.03
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00572598 - TVT Secur: European Feedback Axel Arnaud M.D.
ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00576725-726 - MAUDE Review; Overall TVT Powerpoint
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00589602-607 - Teo R, et al. Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women. Journal of Urology 2011; 185:1350-1355.

**Production Materials**

ETH.MESH.00589602-607 - Teo, R. Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape Obturator for Urodynamic Stress Incontinence in Women. Journal of Urology 2011; 185: 1350-1355
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00596558-560 - Email from Dan Smith to Aaron Kirkemo RE: FW: Scion PA commercial recommendation
ETH.MESH.00642325-331 - Email from Kevin Mahar to Ted Foltyn Cotober 29, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.00642393-399 - Email from Kevin Mahar to Ted Foltyn October 28, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00719241-242 - Draft for review. 2/05/07 Standby Statement
ETH.MESH.00742137-139 - Email from Dharini Amin to Joy Hovsepian March 13, 2007 RE: TVT-Secur v. BSX Prefyx PSS
ETH.MESH.00746179-180 - Email from Harel Gadot to Evridiki Kakoliri September 14, 2006 RE: TVT SECUR Launch activities
ETH.MESH.00746181-182 - Hold for Release Until 9/05/06, 8 a.m. EST Ethicon Introduces New Device to Treat Stress Incontinence
ETH.MESH.00816278 - Email from Lissette Caro-Rosado to Bart Pattyson September 29, 2009 RE: Professional education for TVTS
ETH.MESH.00823138 - Finnegan, S. Clinical outcome of the first cases of the TVT secur in the UK
ETH.MESH.00823421-422 - Gynecare TVT SECUR* System – Australian Postmarket Surveillance Review Meeting October 31 <sup>st</sup> , 2007
ETH.MESH.00823549 - Application FMEA for TVT Secur
ETH.MESH.00831102-110 - Review TVT-Secur versus MiniArc: PUBMED published data – updated July 6, 2010
ETH.MESH.00832121-124 - Email from Mark Yale to Ricci Whitlow November 2, 2007 RE: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.00832226-229 - Email from Mark Yale to David Robinson November 12, 2007 RE: Australia update and telephone call with Prof Frazer
ETH.MESH.00832318 - Email from Axel Arnaud to Christophe Mauge July 17, 2007 RE: Dr. VARMA (UK)
ETH.MESH.00833931-932 - Email from David Robinson to Sharon Shantz January 29, 2007 RE: GYNECARE TVT
ETH.MESH.00834435 - First Human Data for TVT-SECUR* System Support of Life-Cycle Powerpoint
ETH.MESH.00836558-59 - Email string re - TVT-O groin pain
ETH.MESH.00839446-459 - August 23, 2005 Final Report, PSE Accession Number 05-0395, PROJECT Number 67379
ETH.MESH.00839908 - Email from Harel Gadot to Bruno Delacroix August 28, 2006 RE: Prof. Nilsson – TVT SECUR
ETH.MESH.00839918-19 - Email from David Robinson September 20, 2006 RE: TVTS Complaint up to 20 September 06.ppt
ETH.MESH.00840018 - Email from Axel Arnaud to David Robinson December 19, 2006 RE: TVT Secur
ETH.MESH.00840056 - TVT SECUR YTD Findings

**Production Materials**

ETH.MESH.00842256-257 - Email from David Robinson to Joel S. Lippman December 5, 2005 RE: TVT S design val
ETH.MESH.00844901-902 - Email from David Robinson to Kevin Mahar October 18, 2007 RE: Updated Presentation for NPD Meeting – TVT SECUR
ETH.MESH.00845535-536 - Email from David Robinson to Ted Foltyn November 24, 2007 RE: SECUR AU Discussion
ETH.MESH.00845669-670 - Ethicon Memo December 4, 2007 RE: PQI-07-043 TVT Secur release mechanism
ETH.MESH.00846478-479 - Email from David Robinson to Dharini Amin March 13, 2007 RE: TVT- Secur v. BSX Prefyx PSS
ETH.MESH.00848473-474 - Email from David Robinson to Harel Gadot January 10, 2007 RE: Report from Austria
ETH.MESH.00855459 - TVT-Secur (hammock) versus TVT-Obturator: A randomized trial of suburethral sling operative procedures
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858094-95 - Gynecare R&D Monthly Update - March
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00858636-641 - Memo to Dan Smith, Ed Bobertz, Dharini Amin RE: TVT SECUR Lessons Learned Review
ETH.MESH.00858786-787 - Memo to File: Capa #xyz RE: Documentation of the steps taken to understand and resolve issues on TVT SECUR post launch concerns
ETH.MESH.00860142-144 - Email string re-Sample Media TVTO
ETH.MESH.00862176-185 - Prolene Revision History for MS-729-001
ETH.MESH.00862754-757 -6.9.03 Dan Smith Email Re: Double Edged Sword
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466 - Ethicon Expert Meeting-Meshes for Pelvic floor
ETH.MESH.00872132-136 - Email from Dan Smith to Mark Yale September 15, 2006 RE: Potential quality issue on TVT-S
ETH.MESH.00873965-966 - Email from Mark Yale to Gary Borkes December 18, 2009 RE: FW: TVT-S Complant Review
ETH.MESH.00874280 - Email from Mark Yale to Laurent Soulier September 21, 2006 RE: Potential quality issue on TVT-S
ETH.MESH.00874339-340 - Email from Dan Smith to Hanke Sierk March 6, 2007 RE: TVT-Secur CAPA
ETH.MESH.00874349-351 - Email from Dan Smith to Harel Gadot May 29, 2007 RE: TVT SECUR
ETH.MESH.00874445 - TVT-SECUR Quality Board
ETH.MESH.00874516 - Email from Mark Yale to Catherine Beath November 26, 2007 RE: TVT-S Update
ETH.MESH.00874519-520 - Email from Dan Smith to Mark Yale November 26, 2007 RE: TVT-S Update
ETH.MESH.00874627-629 - Email from David Robinson to Mark Yale January 7, 2008 RE: SECUR Markets: TVT SECUR – Critical Steps Guide
ETH.MESH.00875656-657 - Email from Quentin Manley to Mark Yale December 21, 2005 RE: Minutes of meeting: TVT SECUR design validation discussion 20 <sup>th</sup> Dec 2005

**Production Materials**

ETH.MESH.00918015 - Sunoco MSDS 04.13.05
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.00994917-18 - McCabe email re - Sheath Sales Tool
ETH.MESH.01000254-257 - Email from David Robinson to Cheryl Bogardus March 7, 2007 RE: FW: DRAFT of the latest "cookbook" after my trip to Germany
ETH.MESH.01000635-636 - Email from Sergio Gadaleta to John Clay September 6, 2006 RE: FINAL REVISED TVT SECUR Flash Animation Home Page (2696) – For FINAL SIGN OFF
ETH.MESH.01000726-730 - Email from Axel Arnaud to Dan Smith December 19, 2006 RE: TVT-S Cookbooks
ETH.MESH.01037447-455 - Charlotte D. Owens Clinical Report on TVT-S
ETH.MESH.01059148-152 - Gynecare TVT-Secur 2007 Product Complaints Involving Serious Injury
ETH.MESH.01128679-698 - Brochure - Procedural Steps Gynecare TVT SECUR™ System - The Support is Here
ETH.MESH.01130568 - Ethicon, Inc. Worldwide Complaint-Reporting Statement Gynecare TVT Secur™ System
ETH.MESH.01186550-56 - Rosenblatt, P. Update on suburethral slings for stress urinary incontinence.
ETH.MESH.01189392-395 - Summary of sheep and human cadaver labs for development of the GYNECARE TVT SECUR* System
ETH.MESH.01189423-439 - Martin Weisberg; Dave Robinson Clinical Report on TVT-S 2.28.06
ETH.MESH.01193925-930; ETH.MESH.0100644-645 - TVT-Secur: "Hammock" position; Minutes regarding events with Dr. Folke Flarn and training
ETH.MESH.01193957-971 - Executive Summary Preliminary Results of Peri-Operative and 3-Month Outcomes from a world-wide observational registry of tension-free Vaginal Tapes in women with stress urinary incontinence
ETH.MESH.01193973 - A multicenter, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the GYNECARE TVT SECUR* System Tension-free Support for Incontinence 5 week results. David Robinson, MD Medical Director, ETHICON Women's Health & Urology
ETH.MESH.01202101-03 - Email string re - Revised writeup of the DeLeval and Waltregny visit
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203847-869 - Performance Evaluations of A New TVT Single Incision Mesh System for the Treatment of Stress Urinary Incontinence. Daniel J. Smith; Engineering Fellow Ethicon's Women's Health and Urology
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01215019-24 - Tseng LH, et al. Randomized comparison of the suprapubic arc sling procedure vs TVT for stress incontinent women. Int Urogynecol J (2015) 16:230-235.
ETH.MESH.01216820-822 - Email from Dan Smith to Aaron Kirkemo March 23, 2010 RE: Information Regarding Scion
ETH.MESH.01218019 - Design FMEA TVT LCM Project
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01221055-58 - Pariente J-L. An Independent biomechanical evaluation of commercially available suburethral slings- 8.5% particle loss.
ETH.MESH.01222617-54 - Protocol PSE Accession NO. 02-0579-T-2176

**Production Materials**

ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01239657-680 - First Clinical Experience with a Single-incision (TVT Secur®) Tape Procedure for Treatment of Urinary Stress Incontinence
ETH.MESH.01271289-301 - Gynecare TVT with Abdominal Guides Early Clinical Experience
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.0128019 - Design FMEA TVT LCM Project
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01317515-524 - TVT Preventia FMEA [T-2143]
ETH.MESH.01407852 - Ethicon Sarl, Neuchatel Potential Failure Mode and Effects Analysis Process FMEA
ETH.MESH.01409306-348 - Form for Design Requirements Matrix
ETH.MESH.01424029-35 - Cobb WS, et al. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation, Vol 12, No 1 (2005)
ETH.MESH.01592121-134 - Gynecare TVT Secur* System Design Validation Report (Product) Report #TVTSDVLPRD1
ETH.MESH.01736775-791 - Martin Weisberg; Dave Robinson Clinical Report on TVT-S 2.20.06
ETH.MESH.01739544-579 - Clinical Evaluation Report Gynecare (Tension-free Vaginal Tape) TVT Secur* System by David Robinson November 1, 2010
ETH.MESH.01744577-582 - Memo from Dan Smith to Dr. David Robinson RE: Elongation Characteristics of Laser Cut PROLENE Mesh for TVT SECUR February 15, 2006
ETH.MESH.01746858-861 - Email from Harel Gadot to Andrew Beveridge October 1, 2008 RE: TVT World Registry
ETH.MESH.01752532-35 - Mesh design argumentation issues
ETH.MESH.01760362-363 - Email from Michael Woods to David Robinson December 21, 2007 RE: Trial
ETH.MESH.01761352-359 - Email from David Robinson to Bob Roda December 20, 2006 RE: TVT-S Cookbooks
ETH.MESH.01761400-403 - Email from David Robinson to Bob Roda May 10, 2007 RE: RECENT AAVIS MESH USERS FORUM/ TVT REIMBURSEMENT UPDATE (Australia)
ETH.MESH.01763770-772 - Email from David Robinson to Dan Smith September 25, 2006 RE: email
ETH.MESH.01767788-789 - Summary of Preliminary Clinical Results for TVT Secur® System
ETH.MESH.01769881 - Letter to Team RE: Reviewing the Last iteration of the Clinical Strategy for TVT Secur
ETH.MESH.01774812-813 - Meeting Report December 19, 2007 An invention concerning "A lifting thread and technique for percutaneous modeling of soft tissues"
ETH.MESH.01775486-493 - Email from Harel Gadot to Cheryl Bogardus January 8, 2007 RE: TVT-S Cookbooks
ETH.MESH.01777030-036 - Email from David Robinson to Judith Gauld June 20, 2007 RE: Drafted Standard for SUI Slings and POP/AFNOR/ France
ETH.MESH.01782850-852 - Email from David Robinson to Harel Gadot June 20, 2006 RE: Clinical strategy for SECUR
ETH.MESH.01784428-435 - Email from David Robinson to Allison London Brown December 20, 2006 RE: TVT-S Cookbooks
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - Email string re: +M relaxation
ETH.MESH.01802785-786 - TVT Secur, Confirmation lab – Protocol only LAB 5/24/2005

**Production Materials**

ETH.MESH.01802790-791 - TVT Secur, Confirmation lab – Protocol Only LAB 5/31/2005
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01815027-029 - Key Human Cadaver Lab Reports used in the development of TVT SECUR
ETH.MESH.01815103-104 - TVT X Cadaver Lab 12/14/2004 (Results are in BOLD)
ETH.MESH.01815105-110 - TVT X, protocol and completion report 12/28/2004
ETH.MESH.01815111-113 - TVT-U (Results) Cadaver Lab 1/28/2005
ETH.MESH.01815114-117 - TVT Secur, Confirmation lab – Report LAB 5/24/2005
ETH.MESH.01815118-120 - TVT Secur, Confirmation lab – Report LAB 5/31/2005
ETH.MESH.01815135-143 - August 10, 2005 Gynecare TVT* Secur Cadaver Protocol
ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur leading to less retention October 18, 2006
ETH.MESH.01824316-317 - Email from Dan Smith to Eric Gautheir November 6, 2006 RE: FW: TVT-S Complaint review
ETH.MESH.01824402-407 - Email from Dan Smith to Axel Arnaud December 19, 2006 RE: TVT-S Cookbooks
ETH.MESH.01923497 - August 22, 2008 Memo RE: PQI07-041 Issue: Concerns with J&J Australia in regards to anecdotal reports of high post procedure incontinence – 6wks post op to TVT-SECUR procedure.
ETH.MESH.01946236-238 - Email from Dan Smith to David Robinson Marh 7, 2007 RE: DRAFT of the latest “cookbook” after my trip to Germany
ETH.MESH.01946719-721 - Email from Catherine Beath to Mark Yale November 5, 2007 RE: Additional complaints
ETH.MESH.02017152-56 - 02.23.2007 Ethicon Expert Meeting: Meshes for Pelvic Floor Repair
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02106139-140 - Email from Jason Hernandez to Lesley Fonio February 27, 2009 RE: Regional Input to Finalize TVT WORLD Recommendation for Board Meeting on Monday March 2 <sup>nd</sup> .
ETH.MESH.02134271-73 - Draft-Mechanisms of Cytotoxicity of TVT
ETH.MESH.02151813 - TVT-Secur PQI07-041 Quality Board - Follow Up
ETH.MESH.02168828-831 - Minutes of the second meeting on NICE IP review consultation – TVT SECUR 9 November 2007
ETH.MESH.02180759-761 - University of Liege De Leval Confidential Meeting TVT-O Modifications 3.29.04
ETH.MESH.02194843-847 - Email from David Robinson to Ramy Mahmoud November 3, 2007 RE: URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.02200994-995 - February 16, 2006 Memo to Patricia Hojnoski RE: Biocompatibility Risk Assessment for the 510(k) Submission and the CE Mark Design Dossier of GYNECARE TVT Secur
ETH.MESH.02211890 - Bates stamped non-color version - LNE Pore Size Testing of TVT
ETH.MESH.02211890 - Test Report
ETH.MESH.02219584 - Scion PA/SUI Treatment Unmet Needs Exploratory Research - Presented January 22, 2010
ETH.MESH.02229063 - Secur placement.wmv

**Production Materials**

ETH.MESH.02234874-910 - Waltregny Presentation- A modified version of GYNECARE TVT™ Obturator System Tension-free Support for Incontinence with a shorter tape and reduced dissection
ETH.MESH.02237103-104 - Gynecare TVT™ Family of Products Tension-free Support for Incontinence.
ETH.MESH.02248778 - Mechanical vs. Machine Cut - January 19, 2005 Prepared by: Allison London Brown, Gene Kammerer
ETH.MESH.02248778 - Mechanical vs. Machine cut Mesh
ETH.MESH.02249054-077 - September 12, 2005 Memo to Dan Smith RE: Report Amendment 1, PSE Accession Number 05-0396, Project Number 67379
ETH.MESH.02310653 - Selman email with attachment re - Information about FDA notification on use of mesh in pelvic surgery
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02320485-489 - Email from David Robinson to Kevin Mahar January 23, 2007 RE: Portugal and your input regarding the surgical visits.
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340568-591 - TVT Secur IFU
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02341203-13 - TVT Abbrevio IFU
ETH.MESH.02589032 - Powerpoint - Investigating Mesh Erosion in Pelvic Floor Repair Report by Berman, et al. May 18, 2011
ETH.MESH.02592389-390 - Email from David Robinson to David Robinson October 19, 2007 RE: TR: TVT SECUR in the Elderly
ETH.MESH.02594067 - Clinical Outcome of the First Cases of the TVT <i>secur</i> in the UK Dr. S Finnegan, SpR; Dr. P P Fogarty, Cons Ulster Hospital, Belfast
ETH.MESH.02596677-678 - Lammerink, E. Short-term outcome of TVT-Secur
ETH.MESH.02596687 - Fischerlehner, G. TVT-Secur System: One year experience.
ETH.MESH.02596702 - TVT-Secur Workshop Dr. Sepulveda MC Erasmus Rotterdam 27/5
ETH.MESH.02596703-704 - TVT-Secur Workshop Dr. Sepulveda 27/5 Procedural Guidelines for Hammock placement
ETH.MESH.02599329-330 - Email from Piet Hinoul to David Robinson August 2, 2010 No Subject
ETH.MESH.02620914-15 - TVT Issue Report
ETH.MESH.02622276-79 - Issue Report; TVT Retropubic 2001.
ETH.MESH.02654027-028 - TVT-O Issue Report 2006
ETH.MESH.0291609-611 - Clinical Study Report Evaluation of the TVT Secur System for Stress Urinary Incontinence Study Code 300-05-002 12.6 Safety Conclusions – 13 Discussion and Overall Conclusions
ETH.MESH.02916532-541 - Clinical Study Report Evaluation of the TVT Secur System for Stress Urinary Incontinence Study Code 300-05-002 1. Title Page – Page 9 Conclusions
ETH.MESH.03172217 - A Multi-Centre, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the TVT-Secur System M. Karram, MD
ETH.MESH.03185928-931 - Email from Neil David to Harel Gadot October 26, 2007 RE: NICE IP review on Single Incision Sub-urethral slings (TVT Secur)
ETH.MESH.03208548-549 - Email from Piet Hinoul to Judi Gauld January 28, 2009 RE: TVT WORLD AE Report

**Production Materials**

ETH.MESH.03208738 - Email from Jason Hernancez to Julie Bird February 25, 2009 RE: Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday March 2 <sup>nd</sup>
ETH.MESH.03208739 - Powerpoint TVT WORLD Registry Maximizing the investment SBT Feb 2009
ETH.MESH.03235997-998 - Email from Judi Gauld to Jacqueline Russo-Jankewiez December 16, 2009 RE: TVT Secur – Media Standby
ETH.MESH.03258782-783 - Email from Aaron Kirkemo to David Robinson May 13, 2009 RE:
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03367228-232 - Email from Zeb Viana to Ulrika Kohler December 14, 2009 RE: Danish case
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to 11.26.14)
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03463398-407 - Email from Stacy Hoffman to Mary Byerly August 12, 2010 RE: FW: Urogynecological urinary incontinence product contract
ETH.MESH.03590983-1080 - August 10, 2005 Memo to Dan Smith RE: Protocol, PSE Accession Number 05-0396, Project Number 67379
ETH.MESH.03643186 - Ethicon Women's Health and Urology Brand Equity Study Final Report January, 2010
ETH.MESH.03649244-249 - Risk Management Report TVT SECUR System
ETH.MESH.03667696-704 - Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices.
ETH.MESH.03714002-018 - Martin Weisberg Clinical Report on TVT-S 12.2.05
ETH.MESH.03714599-614 - Martin Weisberg Clinical Report on TVT-S
ETH.MESH.03715978-79 - Weisberg email re: TVT Question
ETH.MESH.03751819 - The Science of "What's Left Behind" ...Evidence & Follow-Up of Mesh Use for SUI.
ETH.MESH.03845446-450 - Email from Darryl harkness to Aran Maree October 30, 2007 RE: SECUR update presented in a WW Mktg. Meeting
ETH.MESH.03845464-469 - Email from Aran Maree to Robert Scherini October 31, 2007 RE: SECUR Update presented in at WW Mktg Meeting
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905619-621 - Email from Martin Weisberg to Patirica Hojnoski September 15, 2005 RE: Clinical Expert Report
ETH.MESH.03906976 - Exhibit 2227 - TVOT-04.30.2003-Meeting Report
ETH.MESH.03907468-69 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175-77 - Arnaud email re: Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03913310 - An Audit of the Introduction of TVT Secur in Clinical Practice F Marsh, P Assassa
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03913367 - Debodinance, P. TVT Secur™: More and more minimal invasive. Preliminary prospective study on 106 cases.
ETH.MESH.03913371 - Marsh, F. An Audit of the Introduction of TVT Secur in Clinical Practice.
ETH.MESH.03913651-655 - CDMA Europe Meeting Urinary Incontinence Platform Meeting Minutes June 1, 2007

**Production Materials**

ETH.MESH.03915380 - Axel Arnaud email re Dr. Lucente-TVT Procedure Improvements-Prevention of Overstretching
ETH.MESH.03916905-13 - Plaintiff's Exhibit 3827
ETH.MESH.03921482-489 - Email from David Robinson to Cheryl Bogardus December 21, 2006 RE: TVT-S Cookbooks
ETH.MESH.03921499-1500 - Email from David Robinson to Usman Azam December 19, 2006 RE: TVT Secur
ETH.MESH.03921503-504 - Email from David Robinson to Axel Arnaud December 19, 2006 RE: TVT Secur
ETH.MESH.03921603-605 - Email from Dan Smith to David Robinson December 5, 2006 RE: TVT-SECUR Follow Up on Conference call last week
ETH.MESH.03921606-608 - Email from Dan Smith to David Robinson December 5, 2006 RE: TVT-SECUR follow up on conference call last week
ETH.MESH.03921612 - Email from Ralf Gotter to Harel Gadot November 30, 2006 RE: The more procedures the more problems
ETH.MESH.03921798-799 - Email from Andrew Beveridge to Axel Arnaud October 25, 2006 RE: TVT secure report KOL The Netherlands
ETH.MESH.03921836-838 - Email from Laurent Metz to Sheri Dodd RE: TVT - Secur Registry - Local Activities
ETH.MESH.03922228-230 - Email from Quentin Manley to Dhinagar Subramanian October 25, 2007 RE: NICE IP review on Single Incision Sub-urethral slings (TVT Secur)
ETH.MESH.03922261 - Email from Andrew Beveridge to Ted Foltyn October 3, 2007 RE: AMS Mini Arc
ETH.MESH.03922286-288 - Email from David Robinson to Harel Gadot October 1, 2007 RE: FW: TVT Secur Research
ETH.MESH.03922405 - Email from Andrew Beveridge to Axel Arnaud June 6, 2007 RE: FW: TVT Secur & NICE
ETH.MESH.03922434-437 - Email from Bob Roda to Dharini Amin May 18, 2007 RE: TVT SECUR EU Experts meeting – feedback & future actions
ETH.MESH.03922483-484 - Email from Andrew Beveridge to DL-JNJFRIS EWHU Umbrellas April 26, 2007 RE: GYNECARE TVT SECUR* System Wins Medical Design Excellence Award
ETH.MESH.03922618-619 - Email from David Robinson to Axel Arnaud March 14, 2007 RE: Conf call tomorrow
ETH.MESH.03922619 - A Multicenter, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the GYNECARE TVT SECUR* System Tension-free Support for Incontinence 5 weeks results. David Robinson, MD Medical Director ETHICON Women's Health & Urology
ETH.MESH.03922953 - Email from Xacier Buchon to Fabrice Degeneve January 16, 2007 RE: French data on TVT Secur
ETH.MESH.03923121-122 - Email from Andrew Beveridge to Julie Hocknell February 20, 2008 RE: Trip to Israel
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912 - The History of TVT

**Production Materials**

ETH.MESH.03941623 - de Leval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.03962244 - July 18, 2011 Letter to Surgeon from Piet Hinoul and Aaron Kirkemo
ETH.MESH.04044797-800 - TVT Update Jacquetin, B - Klute, C - Stanton, S - Ulmsten, U - Success and Complications
ETH.MESH.04048515-520 - KOL Interview: Carl G. Nilsson Project Scion Helsinki, Finland 06.18.08
ETH.MESH.04050265-267 - Hinoul Letter regarding De Leval Meeting - Pain in Adductor in young Active Patients
ETH.MESH.04079609 - Gynecare TVT Abbrevio Professional Education (Dr. Babcock).
ETH.MESH.04081189-190 - Meeting Agenda
ETH.MESH.04081301-02 - Memo re - Items need attention
ETH.MESH.04082973-74 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04090133-136 - Email from Meng Chen to Mark Yale November 2, 2007 RE: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.04092868-69 - Email re: 10100080654 and TVT IFUs
ETH.MESH.04093125 - Email from Meng Chen to Bryan Lisa January 29, 2009 RE: FW: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.04094863-64 - 01.29.2009 email from Bryan Lisa to Meng Chen
ETH.MESH.04097335-36 - Meng Chen - Medical Assessment for mesh fraying-Tracking 10100054041
ETH.MESH.04099233-234 - Email from Melissa Day to Luis Blanco September 24. 2008 RE: #1010078150
ETH.MESH.04126732-734 - Gynecare TVT SECUR* Sytem – Postmarket Surveillance Review Meeting November 1 <sup>st</sup> , 2007
ETH.MESH.04126903-906 - Email from Jan Law to Aran Maree November 8, 2007 RE: Hi Jan, I didn't hear back from Malcom at all yesterday. Any chance of this morning? I am at ELT meeting but mobile and e mail are on.
ETH.MESH.04127054-055 - Email from Teng Chuan Khoo to Aran Maree December 5, 2007 RE: Confidential: Australia TCT Secur Issue – Update
ETH.MESH.04127138-139 - Email from David Robinson to Christiana Bielinski January 9, 2008 RE: TGA Meeting
ETH.MESH.04127238 - Communication to Surgeons Regarding the Gynecare TVT Secur™ System March 25 <sup>th</sup> 2008
ETH.MESH.04127331 - Email from Rosalyn Harcourt to Aran Maree September 24, 2008 RE: TVT Secur – re-training
ETH.MESH.04381806-19 - 1997 Literature Review on Biocompatibility of Prolene Sutures and Implants
ETH.MESH.04384112 - Biocompatibility Risk Assessment for the TVT-L Device - June 6, 2001
ETH.MESH.04385209 - October 17, 2005 Memo to Patricia Hojnoski RE: Biocompatibility and Clinical Risk Statement for the inadvertent implantation of the protective cap of GYNECARE TVT Secur in patients
ETH.MESH.04532721-724 - Email from Meng Chen to Carolyn Brennan March 6, 2007 RE: PC# 10100044235 – Dr. [Redacted] (USA – SECUR*) RE: Physician Follow up Request
ETH.MESH.04554734-737 - Letter to Catherine Beath from Thomas Gross RE: Post market Surveillance (PS) Study: PS120095 Trade Name: GYNECARE TVT SECUR SYSTEM 510(K) Number: K052401. Stamped January 3, 2012

**Production Materials**

ETH.MESH.04567675 - Ethicon Gynecare US Commercialization Decision Customer Letter 5/15/2012 from Piet Hinoul and Matt Henderson
ETH.MESH.04567676 - Ethicon Gynecare US Commercialization Decision Distributor Letter 5/15/2012 from Matt Henderson
ETH.MESH.04567677-679 - Ethicon Gynecare US Commercialization Decision Frequently Asked Questions 5/15/2012
ETH.MESH.04567680-681 - Ethicon Gynecare US Commercialization Decision Message from Laura Angelini to Internal WW Associated 5/15/2012
ETH.MESH.04568045 - Letter to Surgeons 6/5/2012 from Piet Hinoul and Matt Henderson
ETH.MESH.04925687-689 - Email from Catherine Beath to Brian Kanerviko January 10, 2012 RE: 522 Order for Surgical Mesh
ETH.MESH.04925709 - Email from Laura Vellucci to Brian Kanerviko January 3, 2012 RE: 522 Guidance Document
ETH.MESH.04929923 - September 22, 2011 Letter to Surgeon from Piet Hinoul and Aaron Kirkemo
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevio
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05133297 - Email from Sheri Dodd to Laurent Mets December 1, 2008 RE: TVT Value Dossier for Emerging Markets
ETH.MESH.05208563-565 - Email from Teng Chuan Khoo to Sateesh Yalisetti October 25, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.05208566-569 - Email from Teng Chuan Khoo to Aran Maree October 25, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.05217098-100 - Modified Prolene Mesh Clearance Letter
ETH.MESH.05217103-144 - Modified Prolene Mesh 510(k)
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05246116-122 - Email from Dan Smith to Allison London Brown January 3, 2006 RE: Results of TVTx preclinical trial
ETH.MESH.05315240-65 - 28 Day Rat Study
ETH.MESH.05316775-812 - Report, PSE Accession NO. 02-0579-T-2133
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05404976 - Commerical-in-confidence Update to the TGA on TVT Secur™ 1 May 2008
ETH.MESH.05406494-497 - Email from Jonathan Meek to Mark Yale Decemeber 17, 2007 RE: TVT Secur* update – POST SCRIPT
ETH.MESH.05473737-739 - October 18 <sup>th</sup> 2005 Amendment 2 to Design Validation Study Gynecare TVT* Secur System
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05498026-028 - Email from Raimo Sump to Dharini Amin October 17, 2005 RE: TVT SECUR Minutes – Team Meeting October 11 <sup>th</sup> 2005_ Agenda October 18 <sup>th</sup> 2005
ETH.MESH.05529274-75 - Gynecare TVT Tension Free Support for Incontinence
ETH.MESH.05529653 - Email string re - Problem statements for TVT brainstorming meeting
ETH.MESH.05530449-478 - December 10 <sup>th</sup> 2005 Product Design Validation Report Gynecare TVT* Secur System

**Production Materials**

ETH.MESH.05534022 - Revision History for TVT Secur application FMEA
ETH.MESH.05559108-109 - Email from Gary Borkes to Dan Smith October 25, 2005 RE: TVT-S Des Val Comments
ETH.MESH.05559898-901 - Email from Dan Smith to Gary Borkes November 18, 2005 RE: Design Validation Review Meeting TVT-S
ETH.MESH.05560563-564 - Email from Patricia Hojnoski to Martin Weisberg September 13, 2005 RE: Clinical Expert Report
ETH.MESH.05560579-80 - Email from Patricia Hojnoski to Martin Weisberg September 15, 2005 RE: Clinical Expert Report
ETH.MESH.05572912-913 - Ethicon Professional Education Description
ETH.MESH.05588123-126 - Stephen Wohler Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05598522 - Ethicon Gynecare US Commercialization Decision US Discussion Guide for Use with Customers 5/15/2012
ETH.MESH.05600916-923 - Ethicon Inc. Background Information Gynecare Pelvic Floor Repair Prodcuts and Gynecare TVT Secure May 29, 2012
ETH.MESH.05641666-670 - Report: Animal Study/TVTx – 12 weeks Explantation, July 30, 2004 by S. Landgrebe November 4, 2004
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05675500 - Ethicon Gynecare WW Commercialization Decision Chuck Austin message to WW associates 5/29/2012
ETH.MESH.05795537-99 - TVT Professional Education Program: Speaker's Guide.
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05916450 - Chronic Pain-Prevention, Future - Bioengineers point of view-D21929 (Powerpoint)
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998805-806 - Piet Hinoul Email RE: ALERTE TVT ABBREVO - Plaintiff's Exhibit 3837
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06050437-438 - Email from Aran Maree to Teng Chuan Khoo December 6, 2007 RE: TVT-Secur Investigation update
ETH.MESH.06050487-488 - Email from Aran Maree to Jan Law November 15, 2007 RE: TVT Secur Follow-up
ETH.MESH.06050497-498 - Email from Aran Maree to Jan Law November 13, 2007 RE: TVT Secur Customers 2007 by Month
ETH.MESH.06050509 - Email from Aran Maree to Darryl Harkness November 20, 2007 RE: TVT Secur discussions Somerville Tues 20 Nov
ETH.MESH.06050795-796 - Memo to TVT Secure DHF #0000120 from Gary Borkes RE: TVT Secur 12 month post launch review August 17, 2007
ETH.MESH.06050830-832 - Email from Jan Law to Aran Maree October 30, 2007 RE: Gynecare TVT SECUR Technical Guide & Updates
ETH.MESH.06050906 - Email from Danielle Hunt to Aran Maree October 31, 2007 RE: TVT-SECUR
ETH.MESH.06050913-919 - Email from Aran Maree to Robert Scherini November 1, 2007 RE: TVT Secur update
ETH.MESH.06051011-1014 - Email from Sateesh Yelisetti to Aran Maree November 2, 2007 RE: URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance.
ETH.MESH.06051155-157 - Email from Aran Maree to David Robinson November 13, 2007 RE: Australia update

**Production Materials**

ETH.MESH.06055060 - Letter to Robyn Chu RE: April 2007 Prostheses List – Application to list Gynecare TVT Secur from Robyn Bilston
ETH.MESH.06070148-153 - Email from aran Maree to Ramy Mahmoud June 2, 2009 RE: TVT-S follow up
ETH.MESH.06150472 - Email from David Robinson to Charman Barham November 9, 2007 No Subject
ETH.MESH.06151215-217 - Email from David Robinson to Cheryl Bogardus March 29, 2007 RE: 6 Month Secur Data
ETH.MESH.06212717-719 - Email from Jonathan Meek to Mark Yale December 17, 2007 RE: TVT Secur* Update
ETH.MESH.06479808-885 - Clinical Study Report Study Code 300-05-002 Draft June 2012
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06706997-7010 - August 23, 2005 Memo to Dan Smith RE: Final report, PSE Accession Number 05-0395, PROJECT Number 67379
ETH.MESH.06707079-083 - Protocol to Evaluate Effect of reinsertion of TVT SECUR device on its Functionality and Device Integrity in a Human Cadaver Model
ETH.MESH.06717961-992 - September 12, 2005 Memo to Dan Smith RE: Report Amendment 1, PSE Accession Number 05-0396, Project Number 67379
ETH.MESH.06860553-558 - Memo RE: Dan's inventive nature and creativity
ETH.MESH.06881576-80 - Email string re-TVTO
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval re IFU
ETH.MESH.06887241-244 - David Waltregny email 7.16.04 re TVT-O
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06887245-246 - Dan Smith Email 7.15.04
ETH.MESH.06893952 - Evaluation of UltraPro Meshes
ETH.MESH.06894461 - Klinge U, et al. Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model. Journal of Surgical Research 103, 208-214 (2002).
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-871 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.06927231-235 - Email string re-Scion PA commercail recommendation
ETH.MESH.07039973-975 - Email from David Robinson to Dan Smith March 22, 2007 RE: TVT World Registry Nilsson
ETH.MESH.07088826-827 - Email from Dhinagar Subramanian to Sheri Dodd January 30, 2008 RE: NICE IP Review – single incision slings.
ETH.MESH.07088877-878 - Email from Judith Gauld to David Robinson May 28, 2008 RE: FW: NICE IP – Single Incision Sub Urethral Slings
ETH.MESH.07104840-841 - Email from Julie Bird to Judi Gauld October 23, 2008 RE: FW: IMPORTANT – Information regarding FDA Publication on the use of Mesh
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07201869-884 - Final Report: Ethicon Study No. SO04/2-2-1 A 3-month pre-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model
ETH.MESH.07201885-903 - LPT Report No. 19285/05
ETH.MESH.07201904-917 - LPT Report No. 19281/05
ETH.MESH.07201918-939 - LPT Report No. 19283/05
ETH.MESH.07226481 - Ethicon (Burkley) response to Clave paper re degradation

**Production Materials**

ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07318311-313 - de Leval Email Re: TVT ABBREVO ALERT - French and English Email and English Translation Certification - Plaintiff's Exhibit 3613
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07387254-257 - Email RE: August Status Report - Gynecare marketing [11.6.13 Exhibit T-3365]
ETH.MESH.07396541-546 - Procedural Pearls & Frequently Asked Questions
ETH.MESH.07455220 - 3.6.2012 Response to email from C. Huntington RE: inertness of polypropylene mesh
ETH.MESH.07876572-07876819 - Traditional 510(K) Notification Gynecare TVT Secur* System K052401
ETH.MESH.07876722-723 - Memo to Herbert P. Lerner from Hector H. Herrera September 22, 2005 RE: K052401 Gynecare TVT Secur System
ETH.MESH.07876820-07876925 - K052401: Response to FDA's Request for Additional Information. Gynecare TVT Secur* System
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003263-278 - TVT Secur IFU
ETH.MESH.08003279-294 - TVT Secur IFU
ETH.MESH.08003279-94 - TVT Patient Brochure
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08117473 - Gynecare TVT Exact Profession Education (Updated).
ETH.MESH.08156958 - Gynecare TVT Tension-Free Support for Incontinence: Advanced Users Forum for the Experienced Clinician.
ETH.MESH.08165497-99 - Meeting Minutes-TVT Development Team Meeting
ETH.MESH.08219141 - Update to the TGA on TVT Secur™ 1 May 2008
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08307644-45 - April 5, 2013 Hinoul email and attached study spreadsheets
ETH.MESH.08311158 - Results - 175 Patients Enrolled and Randomized
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08319128-129 - Ethicon DM Sales Rep Do's and Don'ts [7.11.13 Exhibit T 791]
ETH.MESH.08334244-45 - Email string re: Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08476210 - Fax from FDA requesting changes to labeling
ETH.MESH.08476217-24 - Fax from FDA requesting changes to labelling
ETH.MESH.08568006-12 - Feola A, et al. Stress Shielding-The Impact of Mesh Stiffness on Vaginal Function. Female Pelvic Medicine & Reconstructive Surgery, Vol 17, No 5, Suppl 2, Sept/Oct 2011.
ETH.MESH.09029183-184 - 3 Run Repeatability Study of FSMK0238
ETH.MESH.09238537-541 - Memo to TVT Secure DHF #0000120 from Gary Borkes RE: TVT Secur 12 month post launch review August 17, 2007
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09306898-910 - Incontinence - Plaintiffs Exhibit 4164-R
ETH.MESH.09625731-737 -NDA 16-374 4.16.69
ETH.MESH.09629447-448 - Letter to Dr. Grigsby RE: Prolene Polypropylene Suture, U.S.P., NDA #16-374
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374

**Production Materials**

ETH.MESH.09634081 - Section 6 - Info concerning the quantity of drug distributed
ETH.MESH.09634318 - Prolene Package Insert
ETH.MESH.09634664-77 - 1990 FDA reclassification letter
ETH.MESH.09634664-88 - July 5, 1990 FDA Order
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09744866-67 - TVT Abbrevio
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.10150872 - Supplier Chart
ETH.MESH.10216874-875 - Email string RE: AUGS lecture-content of discussions
ETH.MESH.10226089-091 - Email from Robert Zipfel to Greg Prine August 28, 2007 RE: FW:
ETH.MESH.10281860 - Clinical Expertise TVT Midurethral sling: market Update Prof Ed Slide Deck
ETH.MESH.10575607-13 - Prolene Mesh - Biological Evaluation in Rabbits
ETH.MESH.10982896-909 - LPT Report No. 19282/05
ETH.MESH.11335589-605 - Risk Assessment Summary for the Gynecare TVT SECUR™ System Revision History for 100146510
ETH.MESH.11335728
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report
ETH.MESH.12009027-35 - Gynemesh II-New Mesh Design
ETH.MESH.12831391-393 - September 30, 1987 Letter to Dr. Melveger
ETH.MESH.12831391-404 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12831405 - June 15, 1982 Memo to Dr. Melveger RE: Crack Depth in Explanted Prolene, Polypropylene Sutures
ETH.MESH.14369950 - ISO 14971 - Medical Devices - Application of risk management to medical devices
ETH.MESH.16357664-68 - Therapeutic Products Directorate
ETH.MESH.16416002-004 - Helen Kahlson Email Re: Conversion to Laser Cut TVT
ETH.MESH.17636681-84 - Identification of Issue - Problem Statement-Description
ETH.MESH.17666960-969 - Email from Andrew Meek to nathangoodyear@mac.com July 26, 2007 RE: TVT SECUR Preceptor Meeting 8/24: Somerville, NJ
ETH.MESH.17776990-7011 - Biocompatibility Risk Assessment Report for TVT
ETH.MESH.22138619-628 - Performance Evaluation Report: Corporate Product Characterization
ETH.MESH.22617620-770 - Letter to FDA re K974098 TVT
ETH.MESH.22631022-2029 - TVT - Response to Section 39 Request
ETH.MESH.22634691-92 - Email re - Physician and Patient Labeling Updates to Ethicon Urogynecologic Surgical Mesh - D-8
ETH.MESH.22865906-21 & ETH.MESH.24255174-89 - Email re - Ethicon 510(k) amendments for labeling changes - D-7
ETH.MESH.PM 000067 - TVT- Secur DVD CR 7.12.06
ETH.MESH.PM.000006

**Production Materials**

ETH.MESH.PM.000009
ETH.MESH.PM.000057
ETH.MESH.PM.000068
ETH.MESH.PM.000088
ETH.MESH.PM.000089
ETH.MESH.PM.000090
ETH.MESH.PM.000134
ETH.MESH.PM.000151
ETH.MESH.PM.000154
ETH.MESH.PM.000179 - TVT SECUR Key Tech Points 5.24.2007 Color Original from Prof Ed DVD
ETH.MESH.PM.000179 - TVT Secur_IFU_V5e_2005 to disc_Original from Prof Ed DVD
ETH.MESH01816988-990
ETH.MESH02017152 - Ethicon Expert Meeting-Meshes for the Pelvic Floor Repair
ETH.MESH-08476311 - Cytotoxicity assessment of Ulstem sling
Guidoin R and Chakfe N. Aneurysmal Deterioration of Arterial Substitutes.
Gynecare TVT Secur No Bigger than your Palm. No Less than a revolution brochure.
GYNECARE TVT SECUR* Preceptors Meeting Paris - 13/11/2006 Menahem Neuman, MS Israel
Gynecare TVT SECUR* System Procedural Steps Guideline
Gynecare TVT™ Family of Products Chart
Gynecology Solutions
Heniford DVD Transcription
HMESH_ETH_11642462 - Franchise Regulatory Labeling Guidance - Summary of Changes
Incontinence Platform WW Marketing Team Update August 19 <sup>th</sup> Harel Gadot
JEB Engineering Design Limited - FMEA Potential Failure, Mode and effects analysis (Process FMEA)
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
Kaufman MR. Contemporary role of autologous fascial bladder neck slings: a urology perspective. Controversies in Female Pelvic Reconstruction, 2012, 39(3): 317-323.
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter to Editor re: Ostergard & Sternschuss 2012 Post-implantation alterations of polypropylene in the human.
Librojo updated TVT Declaration (10-23-15) [12 pages]
McCabe email re - Sheath Sales Tool - 464
Miller JM, et al. Clinical Evaluation of Monofilament Polypropylene Suture. Am. Surgeon 33 - 666-70. (1967)
MSDS-Marlex Polypropylenes
Our Credo[8.9.13 A.M. Mitchell Exhibit T-3134
P4117 - Figure 7: Sample 13159, Lot #3405405 (Photograph)
P4118 - Figure 26: J8041-13675 (Photograph)
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
Powerpoint - LCM Project: Photographs Comparing Laser Cut Mesh vs. Mechanical Cut Mesh
Prolene Resin Manufacturing Specifications 1.23.03 [DX23600-R.1-3]
Published clinical data and RCTs - Ethicon.com - 4204-C

**Production Materials**

Seven Year Dog Study - T-2263
Summary of Payments to Experts Lucente to Williams
T-2262 - Deposition Subject Matter Thomas Barbolt Deposition 1.8.14
Te Linde's Operative Gynecology - Plaintiff's Exhibit 3958
T-Pro (Thunder) Pipeline Leadership Team (PLT)
Treatment of SUI with TVT-S (Production 36_000162_2435031_d)
TVT Abbrevio IFU - 01.2015
TVT Exact IFU - 01.2015
TVT IFU - 01.2015
TVT Patient Brochure - 2015
TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator - 01.2015
TVT-Obturator IFU - 01.2015
TVT-SECUR Australian Experience Discussion with TGA Canberra, 9 January 2008

**Company Witness Depositions**

<b>Deponent [Date of Deposition]</b>
Angelini, Laura - 09.16.2013 Deposition Testimony
Angelini, Laura - 09.17.2013 Deposition Testimony
Angelini, Laura - 11.06.2013 Deposition Testimony
Angelini, Laura - 11.14.2013 Deposition Testimony
Arnaud, Axel - 07.19.13 Deposition Testimony
Arnaud, Axel - 09.25.13 Deposition Testimony
Barbolt, Thomas - 01.08.2014 Deposition Testimony
Barbolt, Thomas - 10.09.2012 Deposition Testimony
Beath, Catherine - 07.11.13 Deposition Testimony
Chen, Meng - 10.29.2013 Deposition Testimony
Chen, Meng - 10.30.2013 Deposition Testimony
Hart, James - 09.17.2013 Deposition Testimony
Hart, James - 09.18.2013 Deposition Testimony
Hart, James - 12.20.2013 Deposition Testimony
Hellhammer, Brigitte - 09.11.2013 Deposition Testimony
Hellhammer, Brigitte - 09.12.2013 Deposition Testimony
Hinoul, Piet - 01.13.2014 Deposition Testimony
Hinoul, Piet - 01.14.2014 Deposition Testimony
Hinoul, Piet - 01.15.2014 Deposition Testimony
Hinoul, Piet - 02.01.16 Carlino Testimony Played in Court
Hinoul, Piet - 04.05.2012 Deposition Testimony
Hinoul, Piet - 06.26.2013 Deposition Testimony
Hinoul, Piet - 06.27.2013 Deposition Testimony
Hinoul, Piet - 09.18.2012 Deposition Testimony
Holste, Joerg - 07.29.2013 Deposition Testimony
Holste, Joerg - 07.30.2013 Deposition Testimony
Holste, Joerg - 12.14.2012 Deposition Testimony
Holste, Joerg - 12.15.2012 Deposition Testimony
Isenberg, Richard - 11.05.13 Deposition Testimony
Isenberg, Richard - 11.06.13 Deposition Testimony
Kammerer, Gene - 12.03.2013 Deposition Testimony
Kammerer, Gene - 12.05.2013 Deposition Testimony
Kirkemo, Aaron - 01.06.14 Deposition Testimony
Kirkemo, Aaron - 01.07.14 Deposition Testimony
Klinge, Uwe - 11.04.2015 Deposition Testimony
Klosterhalfen, Bernd - 02.02.2014 Deposition Testimony
Lamont, Daniel - 09.11.2013 Deposition Testimony
Nager, Charles - 01.14.2016 Deposition Testimony
Nager, Charles - 06.10.2014 Deposition Testimony
Owens, Charlotte - 06.19.13 Deposition Testimony
Owens, Charlotte - 06.20.13 Deposition Testimony
Robinson, David - 07.24.2013 Deposition Testimony
Robinson, David - 07.25.2013 Deposition Testimony
Robinson, David - 09.11.2013 Deposition Testimony
Rosenzweig, Bruce - 01.14.2016 Deposition Testimony
Rosenzweig, Bruce - 12.22.2015 Deposition Testimony

**Company Witness Depositions**

Rovner, Eric - 01.14.2016 Deposition Testimony
Rovner, Eric - 08.26.2014 Deposition Testimony
Smith, Dan - 08.20.2013 Deposition Testimony
Smith, Dan - 08.21.2013 Deposition Testimony
Weisberg, Martin - 02.03.16 Carlino Testimony Played in Court
Weisberg, Martin - 05.24.2012 Deposition Testimony
Weisberg, Martin - 05.31.2013 Deposition Testimony
Weisberg, Martin - 08.09.2013 Deposition Testimony
Weisberg, Martin - 11.12.2015 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony

**Other Materials**

<b>Publically Available</b>
2007 NIHCE Interventional procedure overview of single-incision sub-urethral short tape insertion for stress urinary incontinence in women.
2012 ABOG - Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 Update - AUA SUI Guidelines- Appendices A11 and A16 (re Complications)
2013 Oct. AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of SUI
2013 Sept. NICE 171 Guideline - The management of urinary incontinence in women
2014 Jan - AUGS-SUFU MUS Position Statement APPROVED 1 3 2014
2014 July - IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
2014 Mar 12 - AUGS SUFU Provider FAQs MUS for SUI
2015 ACOG, AUGS Practice Bulletin Summary of 155 - Urinary Incontinence in Women (replaces 63 from June 2005)
2015 AUA. A Monograph from the Urology Care Foundation. SUI. Update 2015
2015 Mar EAU Guidelines on Urinary Incontinence
2015 SCENIHR Report, EU Commission FULL - The safety of surgical meshes used in Urogynecological surgery.
21 CFR 801.109
21 CFR 801.109(c) - Device Labeling
21 CFR 860.7
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
7/13/11 FDA: Surgical Placement of Mesh to Repair Pelvic Organ Prolapse Poses Risks.
A Comparative Transobturator Sling Matrix - Boston Scientific <a href="http://www.pelvic-floor-institute.com">www.pelvic-floor-institute.com</a> 2012
A Monograph from the Urology Care Foundation: Stress Urinary Incontinence.
A Summary of the evidence on the benefits and risks of vaginal mesh implants. October 28, 2014
ACGME Program Requirements for Graduate FPMRS, July 1, 2014.
ACGME Program Requirements for Graduate Medical Education in FPMRS
ACGME Program Requirements.
ACOG Chronic Pelvic Pain
ACOG Committee Opinion 498 Adult Manifestations of Childhood Sexual Abuse August 2011 (Reaffirmed 2015)
ACOG Frequently Asked Questions - When Sex Is Painful
ACOG Surgery for Stress Urinary Incontinence FAQ
ACOG, AUGS Practice Bulletin 155 (replaces 63 from 2005) Urinary Incontinence in Women.
ACOG, AUGS Practice Bulletin Summary of 155 (replaces 63 from 2005) Urinary Incontinence in Women. November 2015.
AUA (2011) - Position Statement on the Use of Vaginal Mesh for SUI
AUA Expert Witness Affirmation Statement
AUA Expert Witness Testimony In Medical Liability Cases.
AUA Guideline for the Surgical Management of Female Stress Urinary Incontinence Update (2009)
AUA National Medical Student Curriculum Urinary Incontinence
AUA National Medical Student Curriculum, updated August 2012
AUA Position Statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence [November 2011, October 2013 revised].
AUA Position Statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence [November 2011].

**Other Materials**

AUGS SUFU Frequently Asked Questions by Patients Mid-urethral Slings for Stress Urinary Incontinence
AUGS 2016 (eposter) Serious adverse events with transvaginal mesh are rare.
AUGS Blogs Organizations Lend their Support to Mid-urethral Slings
AUGS Blogs: Midurethral Slings: A Treatment Worth Protecting.
AUGS FAQs-Mid-urethral Slings for SUI-DX23540
AUGS Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders
AUGS Practice Bulletin Summary, Number 155: Urinary Incontinence in Women [November 2015].
AUGS President's Perspective: Organizations Lend their Support to Mid-urethral Slings. June 23, 2016.
AUGS Resident Learning Objectives
AUGS SUFU Frequently Asked Questions by Patients MUS for SUI
AUGS SUFU Frequently Asked Questions by Providers MUS for SUI
AUGS SUFU Position Statement on MUS for SUI
AUGS/SUFU Frequently Asked Questions by Patients: Midurethral Slings for Stress Urinary Incontinence.
AUGS/SUFU Frequently Asked Questions by Providers: Midurethral Slings for Stress Urinary Incontinence.
AUGS/SUFU Position Statement of Mesh Midurethral Slings for Stress Urinary Incontinence.
AUGS-SUFU MUS Position Statement updated June 2016
Brief Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
CFR - Code of Federal Regulations Title 21. Current as of 4/1/15
Deposition Subject Matter-Design and Development of Mesh Products
Device Labeling Guidance
EAU Guidelines on Urinary Incontinence. Urinary Incontinence - partial update March 2015
EU Commission Fact Sheet - (based on 2015 SCENIHR Report) The safety of surgical meshes used in Urogynecological surgery.
EU Commission Fact Sheet 2015
European Commission: The safety of surgical meshes used in urogynecological surgery [December 2015].
Evidence Pyramid
FDA - Device Labeling Guidance #G91-1 March 1991
FDA Considerations about Surgical Mesh for SUI [03.27.2013].
FDA Executive Summary: Reclassification of the Urogynecologic Surgical Mesh Instrumentation. Gastroenterology-Urology Medical Devices Advisory Panel [02.26.2016].
FDA Executive Summary: Surgical mesh for treatment of women with POP and SUI [09.08.2011]
FDA Implants and Prosthetics
FDA News Release: Surgical Placement of mesh to repair pelvic organ prolapse poses risk [07.13.2011].
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. [10/20/08]
FDA Questions (Reclassification of Urogynecologic Surgical Mesh Instrumentation), February 26, 2016.
FDA Questions: Reclassification of the Urogynecologic Surgical Mesh Instrumentation.
FDA Reclassification of Urogynecologic Surgical Mesh Instrumentation, February 26, 2016.
FDA Statement re Considerations about Surgical Mesh for SUI; 2013 Mar 27

**Other Materials**

FDA Stress Urinary Incontinence
Female SUI Procedures
Final Appraisal Determination Tension Free Vaginal Tape Gynecare TVT for Stress Incontinence. National Institute for Clinical Excellence (2003)
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee: Medical Devices Classification/Reclassification. February 26, 2016
Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update.
ICS Fact Sheet 2015
IUGA Interstitial Cystitis and Painful Bladder Syndrome (2011)
IUGA Low-Dose Vaginal Estrogen Therapy (2011)
IUGA Mid-urethral sling (MUS) procedures for stress incontinence (2011)
IUGA Position Statement on Midurethral Slings for Stress Urinary Incontinence.
IUGA Position Statement on MUS for SUI (2014)
Librojo updatd TVT Declaration (10-23-15)
NICE Clinical Guideline 171: Urinary Incontinence: The management of urinary incontinence in women [September 2013].
Obstetrics & Gynecology Devices Panel September 8-9, 2011, Summary Day 1 Surgical Mesh for Repair of Pelvic Organ Prolapse (POP)
Oxford Levels of Evidence Pyramid for Practitioners_from Oxford website
Oxford Levels of Evidence; <a href="http://www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg">www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg</a>
Piet Hinoul September 18, 2013 Clinical Evaluation Report GYNECARE (Tension-free Vaginal Tape) TVT™ SECUR System
RANZOG and UGSA 2014 Position Statement
RCT Pyramid
SCENIHR Opinion on the safety of surgical meshes used in urogynecological surgery. [12.03.2015].
Slide re Dr. Hinoul - Ethicon Medical Director - Rosenzweig 64
Subjective parameters and objective outcome measures used in the studies included in the systematic review
Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence FDA Executive Summary Obstetrics & Gynecology Devices Advisory Committee Meeting September 8-9, 2011
The Kings Health Questionnaire
Tincello Poster - Twelve-month objective and subjective outcomes from a world-wide registry of Tension-free Vaginal Tapes in Women With Stress Urinary Incontinence
<b>OTHER MATERIALS</b>
Batiste Trial - Plaintiff's Opening Presentation.
Bruce Rosenzweig Expert Report from Kathryn McGee Case - January 15, 2016
Deposition of Aran Maree July 23, 2013 Volume II pages 344-485
Deposition of Ramy Mahmoud July 16, 2013 Volume II pages 339-733
Excerpts from the Deposition of Kimberly Kenton, M.D. taken on March 25, 2016.
Pence Direct Slides
Perry v. Ethicon Closing Statement [02.23.2015].
Yale Depo 8.8.13 Pages 558-569

**MDL Wave Cases**

<b>Depositions</b>
Elliott, Daniel (TVT-S General) - 3.6.16
Elliott, Daniel (TVT General) - 9.26.2015
Parisian, Suzanne (TVT-S General) 3.8.16
Rosenzweig, Bruce - (Magee) 2.04.2016
Rosenzweig, Bruce - (Lewis) 11.04.2013
Rosenzweig, Bruce (Engleman) 1.17.2017
Rosenzweig, Bruce (Huskey/Edwards) 3.24.2014
Rosenzweig, Bruce (Ramirez) 3.31.2016
Rosenzweig, Bruce (Susan Smith) 8.31.2016
Rosenzweig, Bruce, M.D. - (TVT General) 9.22.2015
Rosenzweig, Bruce - (Carlino) 1.13.2016
Rosenzweig, Bruce - (Carlino) 1.14.2016
Rosenzweig, Bruce - (Carlino) 12.22.2015
<b>Expert Reports</b>
Elliott, Daniel (TVT-S General) - 01.25.2016
Elliott, Daniel (TVT General) - 2.1.2016
Elliott, Daniel (Supplemental TVT General) 1.2017
Jordi, Howard (General) - 02.01.2016
Klinge, Uwe (POP General) - 11.17.2015
Klinge, Uwe (TVT General) - 11.16.2015
Parisian, Suzanne (TVT-S General) - 01.30.2016
Plaintiff expert reports and materials cited in Wave general reports of Elliott and Rosenzweig
Rosenzweig, Bruce (General) - 06.09.2014
Rosenzweig, Bruce (Huskey/Edwards) - 02.21.2014
Rosenzweig, Bruce (Lewis/Brown) - 10.14.2013
Rosenzweig, Bruce (MDL Design Defect) - 08.24.2015
Rosenzweig, Bruce (Ramirez) - 04.24.2015
Rosenzweig, Bruce (TVT Supplemental General) - 01.06.17
Rosenzweig, Bruce (TVT, TVT-O Notice of Adoption of Prior Reports) - 12.15.2015
Rosenzweig, Bruce (TVT-S General) - 01.22.2016